UNQUALIFIED DOCTORS PERFORMING COSMETIC SURGERY: POLICIES AND ENFORCEMENT ACTIVITIES OF THE FEDERAL TRADE COMMISSION—PART II

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES, AND ENERGY

OF THE

COMMITTEE ON SMALL BUSINESS
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UNQUALIFIED DOCTORS PERFORMING COSMETIC SURGERY: POLICIES AND ENFORCEMENT ACTIVITIES OF THE FEDERAL TRADE COMMISSION—PART II

WEDNESDAY, MAY 31, 1989

House of Representatives,
Subcommittee on Regulation,
Business Opportunities, and Energy,
Committee on Small Business,
Washington, DC.

The subcommittee met, pursuant to notice, at 1:00 p.m., in room 2359-A, Rayburn House Office Building, Washington, DC, Hon. Ron Wyden (chairman of the subcommittee) presiding.

Chairman Wyden. The subcommittee will come to order.

Today, the subcommittee continues its hearings into cosmetic surgery and the advertising practices used to promote it.

This surgery is a phenomenally popular multibillion-dollar-per-year business. One procedure, liposuction, the surgical removal of fat, was performed 1,000 times in 1981 and will be performed 250,000 times in 1989. A so-called cosmetic surgeon can buy $4,000 of equipment in the morning, cover equipment costs with a couple of liposuction procedures that afternoon, and start generating profit the next day.

Fueling the huge growth of cosmetic surgery has been an enormous wave of hard-sell advertising. Advertising techniques previously reserved for hawking food blenders and real estate schemes now promote and hype acid peels, tummy tucks, face-lifts, and a dozen other sought-after procedures. The subcommittee has reviewed hundreds of these ads, and to call many of them huckstering is to be too complimentary.

The Federal Trade Commission is the Federal agency charged with protecting the American people from false and deceptive advertising. The current Chairman of the Commission, Daniel Oliver, asserts in his statement today that the agency is carrying out its statutory responsibilities, and that the views he espouses with respect to medical care are consistent with the policies of his predecessors.

The chairman of this subcommittee disagrees. Past Federal Trade Commissions tried to stop self-regulation by the medical profession, but they did not try to impede State regulators attempting to protect the public.

Past Federal Trade Commissions tried to stop medical providers from fixing prices, but they did not create novel theories about the antitrust laws to justify Federal activity. Past Federal Trade Commissions moved against deceptive consumer practices like the before-and-after ads used to hype cosmetic surgery, but this one has simply diddled.

The chairman of this subcommittee believes that competition has an important role to play in the American health care system, and I believe that responsible advertising that allows consumers to make more informed choices about health care services is surely in the public interest.

But it is my view that these sensible principles have been bent and warped. As a result, there is now so much deceptive and misleading information about cosmetic surgery, and medicine in general, that it is actually harder for consumers to make informed choices about health care services.

Under the FTC's approach, it is more difficult to distinguish between good and bad medical practitioners, and harder for consumers to exercise their marketplace power, and for marketplace forces to drive up the quality of health care.

There are many abuses in cosmetic surgery advertising where the FTC has failed to act. Besides the before-and-after ads, there have been abuses of board certification claims by practitioners, and distorted representations of the safety of various procedures. Mr. Oliver now says that some of these issues deserve study, but this chairman believes that it is time to act to protect the public.

There is another significant problem with the FTC's approach. Mr. Oliver has tried to make the States, not the Federal Government, take the lead in areas that the States say they are powerless to deal with, such as the interstate franchising of heavily advertised procedures. This is of particular distress to me, because not long ago, one of my constituents, Mary Church of Portland, OR, answered an ad offering one of these procedures.

Mrs. Church died following complications from a so-called simple, safe, nonsurgical procedure, the chemical face-lift, attempted by one of these franchise doctors. The doctor later lost his license. But that is obviously of little comfort to Mrs. Church's friends and relatives.

Mr. Oliver's testimony today has been rejected by a majority of the Federal Trade Commission in a vote last week. It is rejected by many of the State regulators, several of whom will describe today how the FTC has hampered their efforts to protect the public. At our last hearing on April 4, patients and medical providers also spoke out against these policies.

President Bush has the opportunity to change direction at the FTC. This hearing is being held so that there can be a current analysis of FTC's policies with respect to health care and, hopefully, a foundation laid for FTC consumer protection initiatives that are truly in the public interest.

This is a matter of great importance to the American people. Several weeks ago, Dr. Frank Young, Commissioner of the Food and Drug Administration, told this subcommittee that medical fraud accounts for $10 billion to $40 billion in losses per year in this country. False and deceptive advertising plays a significant role in spreading this snake oil, and that is why this subcommittee will continue to work for policies that make health care more accessible and more affordable.

As Justice Potter Stewart warned, we

> are not dealing with traders in commodities but with vital interests of public health and the profession treating bodily ills and demanding different standards of conduct from those which are traditional in the competition of the marketplace.

Justice Stewart said safeguards are essential,

> not only against deception but against practices which would tend to demoralize the profession, forcing its members into an unseemly rivalry which would enlarge the opportunities of the least scrupulous.

We welcome today's witnesses, and before we proceed to our witnesses, I want to recognize our colleagues for their statements. I am particularly pleased that our ranking Republican, and a close personal friend of this member, Mr. Broomfield is here. He has very extensive responsibilities, as well as being the ranking Republican on the Foreign Affairs Committee, and we are very pleased to have our colleague and welcome any statement he would care to make.

Mr. **Broomfield**. Thank you very much, Mr. Chairman.

This is truly a fascinating area of inquiry, and I certainly want to applaud you personally for holding these hearings. I want to thank the witnesses who have taken time out of their schedule to appear before this subcommittee today, in particular Chairman Daniel Oliver of the Federal Trade Commission and Congressman Tom Campbell, who would like to add his expertise to these proceedings.

Mr. Chairman, as you know, Tom Campbell has worked at the Federal Trade Commission as the Director of its Bureau of Competition from 1981 through 1983.

Malpractice, deceptive advertising, and other anticonsumer issues should receive, and they are receiving now, your help and national focus. When we can locate these problems, definite action must be taken to see that Federal and State authorities work together to protect the consumer.

As I understand it, the focus of our hearing today will center around deceptive advertising by cosmetic surgeons. One of the first questions I had deals with the size of this problem. It seems logical that any Federal involvement be based on the size of the issue at hand.

I think my colleagues here will agree that the percentage of successful, completed, cosmetic procedures should be a major factor in the end product of these hearings. Apparently, there is a professional controversy within the confines of the cosmetic surgery and the Federal Government must remain the impartial regulator.

We should give our assurances to all the physicians involved that the qualified and the competent will be allowed to practice.

Ultimately, we are here to protect the consumer. We are responsible to the consumer for instituting fair, productive regulation. Deceptive advertising and incompetent physicians should be eliminated from the medical profession. But in our attempts to regulate, let's not kill the patient, in this case the well-trained surgeon, who makes a very positive contribution to society.

Mr. Chairman, thank you once again for this opportunity to be a part of these hearings.

Chairman **Wyden**. Well, I again want to thank my colleague, and it will be a special pleasure to have a chance to pursue these issues with him.

Let me recognize our other colleagues. The gentleman from Missouri, Mr. Hancock.

Mr. **Hancock**. Thank you very much, Mr. Chairman.

Today, this subcommittee will question witnesses, principally the Federal Trade Commission, on the subject of medical advertising and effects of misleading advertising on the consumer. At our first hearing on cosmetic surgery back in April, I stated that I saw this subcommittee's role in this matter as to ensure that reasonable competition existed in the medical profession.

I defined reasonable competition as a combination of choice and safety providing the medical consumer with the utmost benefit. At today's hearing, this mandate is even more important as we are examining one of the most principal tolls of competition available in the medical marketplace—advertising.

Now, make no mistake, those who suffer because of medical abuse should receive full opportunity to recover damages and air their complaints, and these victims should also have the comfort of knowing that others will not be victimized by this same practitioner.

I think everyone here today would agree with this. But I hope that in our rush to help those taken advantage of by the dishonest or incompetent medical practitioner, we will also recognize that the vast majority of doctors are honest people doing good work. We must not neglect the average medical consumer who is treated by this vast majority.

Misleading advertising and medical malpractice are not synonymous. A bad ad does not directly produce a bad surgical procedure. An unqualified practitioner could employ perfectly legitimate advertising, or for that matter, not advertise at all, and still perform bad surgeries. Similarly, it is conceivable that a qualified surgeon could place a misleading ad. So, the question we should ask today is, "Without advertising, would medical malpractice cease to exist?"

At the heart of the previous question is whether or not advertising on the whole benefits the consumer. The FTC has conducted a fairly exhaustive study of the effect of advertising on the cost of medical services, which is very insightful as to this relationship.

Conducted in 1980, the *Optometry* case shows quite convincingly that the price of optometric services was lower in markets with advertising than those without, while quality of care was comparable. This study showed convincingly that consumers benefited considerably through proper advertising and the competition it brings forth.

Undeniably, some misleading advertisements are being placed in the medical profession today. It is important that this subcommittee examine which authorities are empowered to police this area and, from a public policy perspective, who should prosecute wrongdoers. The Federal Trade Commission is limited by the FTC Act of 1974 to matters in or affecting interstate commerce. Most doctors practice and advertise locally, so the authority of the FTC to police all such ads is questionable.

In a larger sense, the question should be asked, "Is the Federal Government best equipped to regulate principally local matters?" The American Bar Association recommended in a study on the role of the FTC that when the FTC "learns of a questionable advertisement with a principally local effect, the FTC should refer the matter to the State and offer to help." Our inquiry of the FTC should then focus on whether it has indeed been helping the States.

In conclusion, the problem of misleading medical advertising is deserving of consideration. However, this problem begets no easy answers. The public benefits from advertising on the whole, and we must be sure that actions to curb misleading ads do not harm the public by restricting healthy competition.

I hope the witnesses appearing today will address these concerns. I look forward to their testimony, and I thank you, Mr. Chairman, for calling this hearing. Thank you.

Chairman WYDEN. I thank my colleague, and also very much appreciate this participation, his involvement.

Our colleague from Colorado, Mr. Hefley.

Mr. HEFLEY. No questions or statement at this time, thank you.

Chairman WYDEN. All right, with that, we will proceed right to our witnesses. Panel one, the Honorable Richard Gannon, executive director, Board of Healing Arts, Topeka, KS, accompanied by Lawrence Buening, Jr., general counsel; Dr. Hugh Johnston, chairman, Board of Medical Examiners, State of Oregon, Portland, OR, accompanied by John Ulwelling, executive secretary, Board of Medical Examiners.

Gentlemen, it is a pleasure to have all of you here. I would like to note at the outset that I was born in Wichita, KS, and now am a Congressman from Oregon. So, two of the very special places in my heart are recognized on this panel.

It is the practice of our subcommittee to swear all the witnesses that we have before us. Do any of you four gentlemen have any objection to being sworn today?

Mr. GANNON. No, sir.

Mr. BUENING. No, sir.

Dr. JOHNSTON. No, sir.

Mr. ULWELLING. No, sir.

Chairman WYDEN. Please raise your right hand.

[Witnesses sworn.]

Mr. GANNON. I do.

Mr. BUENING. I do.

Dr. JOHNSTON. I do.

Mr. ULWELLING. I do.

Chairman WYDEN. We will make a copy of your prepared remarks a part of the record in their entirety, and if you could summarize your views in 5 minutes or so, that would be particularly helpful to us. Why don't we begin with you, Mr. Gannon? I gather it was your intent that you testify and your associate, Mr. Buening, be available for questions.

TESTIMONY OF RICHARD G. GANNON, EXECUTIVE DIRECTOR, KANSAS STATE BOARD OF HEALING ARTS, ACCOMPANIED BY LAWRENCE BUENING, JR., GENERAL COUNSEL

Mr. **Gannon**. That is accurate. However, I may have some difficulty summarizing this material in 5 minutes.

Chairman **Wyden**. Well, we will try to consider that. I know with the number of members that we have today, and the lateness of the hour, we will have to stick pretty close, but you proceed. We appreciate your involvement.

Mr. **Gannon**. Mr. Chairman and members of the subcommittee, I am Richard G. Gannon, executive director of the Kansas State Board of Healing Arts. Also with me today is Lawrence T. Buening, Jr., the general counsel for the board.

Being recently and voluntarily retired from the Kansas Senate, my experience provides me knowledge of the legislative committee forum. Consequently, I realize the demands on your time and sincerely appreciate this opportunity for the State of Kansas to provide her views and concerns about false and deceptive advertising by health care professionals.

In the 12-year tenure with the Kansas Senate and involvement with the National Conference of State Legislatures, I have had the opportunity to lobby Congress on numerous occasions. As I recall, in those lobbying attempts with my legislative colleagues, we seem to either be asking you for more Federal funding or espousing State rights.

Today, I am using this arena to request your assistance in the area of false and deceptive medical advertising. This issue is far too complex and great for the States to deal with on an individual basis. Therefore, we must have the efforts of the 50 States working in concert through the Federal Government.

The Kansas State Board of Healing Arts is the agency in the State of Kansas which is vested with the responsibility and authority to regulate various health care professionals. It is an independent agency in the executive branch of government, and it is comprised of 15 members appointed by the Governor.

The board licenses or registers medical doctors, osteopathic doctors, doctors of chiropractic, doctors of podiatry, physical therapists, physical therapy assistants, physician assistants, respiratory therapists, occupational therapists, and occupational therapy assistants. These groups make up approximately 11,000 individuals who are regulated by the board.

For the past several years, the Kansas Legislature has taken numerous steps to strengthen the ability of the board to ensure the competency and qualifications of these practitioners in the State. These steps have included additional legal, investigative, and administrative staff, substantial increases in appropriations, and the strengthening of the laws under which disciplinary measures may be taken.

As I had mentioned earlier, I served 12 years in the Kansas State Senate prior to resigning my seat July 11, 1988, to take over as the board's first full-time executive director. In the 10.5 months I have served in this capacity, I have had an opportunity to see hundreds of complaints alleging incompetency or unprofessional conduct by Kansas State health care providers.

I wish to advise this panel that the State Board of Healing Arts in Kansas takes very seriously its charge to protect our citizens against unprofessional, incompetent, and unqualified practice as well as from unprofessional conduct, as that term is defined by Kansas statute.

In the first 10.5 months of the fiscal year which began July 1, 1988, the board has received 476 formally logged and/or investigated complaints. In this same time period, the board has taken 80 disciplinary actions.

Based upon the numbers of health care providers who practice in our State, I firmly believe that you will find that the number of disciplinary actions taken by the Kansas Board these past 10.5 months will rank among the highest in the Nation when compared to the number of doctors who actively practice in our State.

Although the board has aggressively investigated complaints and has taken a number of disciplinary actions, this should not negatively reflect on the quality of medical care being provided by the vast majority of practitioners.

The typical doctor in Kansas is well educated, dedicated, and deeply concerned for the welfare of patients. The people of the State of Kansas are rightfully proud of the facilities which exist for medical education.

Research and treatment in a number of medical areas are as advanced as anywhere in the world. I feel that Kansas has set a high standard of medical care and provides some of the best medical care in the Nation, and this includes some of the country's leading specialists, teaching institutions, and hospitals.

In my time with the board, I have seen the number of complaints and concerns about advertising practices multiply. However, there only have been a handful of cases in which questions as to the propriety of advertising has been a primary issue.

The board's disciplinary counsel finds it is neither efficient nor productive to build a case on advertising alone. This is because various FTC and court rulings have made it extremely difficult to discipline a doctor solely on the basis of advertising with the exception of the most blatant violations.

Fortunately, in most cases, doctors who have committed violations provide us with the luxury of prosecuting on various infractions. Yet, the number of complaints and concerns that are being raised solely about advertising is definitely on the increase.

One recent case in which the board publicly censured two doctors for deceptive and misleading advertising has resulted in a great deal of public attention. It has even resulted in a call from an attorney with the Federal Trade Commission to our general counsel, Mr. Buening.

To the best of our staff's recollections, this is the first time the Federal Trade Commission has had occasion to contact the board office in, at least, the last 5 years. It appeared from the telephone conversation that the Federal Trade Commission was questioning the reasons the board had publicly censured these two doctors, to ensure that the board had not in some manner illegitimately placed restraints on truthful advertising.

At almost every meeting of the Federation of State Medical Boards and the National Clearinghouse on Licensure, Enforcement, and Regulation of the Council of State Governments, educational sessions are devoted to antitrust and competition policies. Our board is certainly of the Federal Trade Commission rulings which state it has jurisdiction over State regulatory and that it may scrutinize board actions from an antitrust standpoint.

In doing the research for my appearance, it was interesting to find that in 1983, then State Senator Jan Meyers, now Congresswoman Meyers, chaired the Senate Public Health and Welfare Committee in the Kansas Legislature, which considered and enacted SB 294 concerning advertising.

The bill was requested by the Kansas Medical Society since the prior statute on advertising had been declared unconstitutional by a Federal Court, and the board was unable to discipline any doctor for any type of advertising. With the changes made by the 1983 Kansas Legislature, the board has been directed to take action to prevent and prohibit false, fraudulent, deceptive, and misleading advertising by health care professionals it regulates.

The board seriously and aggressively takes the actions necessary to meet this statutory obligation. Yet, contacts by Federal agencies whenever such actions are taken does cause consternation and may have a chilling effect if the result is to become embroiled in actions brought by the Federal Trade Commission.

In the particular case I have been describing, a chemical process known as exodermology, also known as endodermology, is used. This application of phenol acid constitutes a chemical skin peel of the face. The board had two physicians serve as consultants in this case. One specializes in plastic and reconstructive surgery, as well as cosmetic and hand surgery and the other consultant is a dermatologist.

Both of our consultants found that the advertising materials reviewed were misleading as they deceptively conveyed the degree of results of cosmetic improvement that could be expected from exodermology alone, and certainly from the passage of only 8 days from the date the treatment was performed.

The photographs utilized in the advertising material were purported to be "unretouched." However, in discussing this with the physicians who were publicly censured, they indicated that they did not know these patients, they were not patients on whom they had performed exodermology, and, further, they had no real knowledge whether the photographs were unretouched or not.

There is a possibility that the patients in the photographs had actually undergone plastic surgery rather than just the exodermology process. The board, in finding the advertising materials to be deceptive and misleading, based its finding on the use of written representations and photographs which depicted results, that is, "miracles," claimed to be achieved from exodermology after just 8 days.

These results as claimed, in the opinion of the board, simply could not occur.

I want to emphasize that the State of Kansas, like every other State in the Nation, does not license physicians by particular specialties. Rather, an individual is licensed to practice medicine and surgery, and if they do not perform such in a competent fashion, they may be disciplined for a variety of statutory reasons.

In the case at hand, there was no finding by the board that the process of exodermology itself was an improper procedure. A type of phenol process for the skin peel may be used by qualified skin surgeons and dermatologists.

However, it is interesting to note that the two individuals who were publicly censured were general practitioners and had but a very minimal amount of training and education in the process of exodermology. After talking with your staff, a question has arisen as to whether the training these two doctors received in exodermology was even provided by a licensed physician.

I think it is important to note that the public censure of these two doctors has had apparently no effect on the ability of these doctors to advertise. To emphasize this point, I have attached to this testimony advertisements placed by them which appeared in the Wichita Eagle-Beacon following the public censure.

The difficulties faced by the Kansas State Board of Healing Arts in disciplining practitioners for false advertising are not unique to the State of Kansas nor do they end with advertising. Infrequently, suspect advertisements are brought to the attention of the Kansas Board involving licensees who, in attempting to advertise their services, overstep the bounds of what is legally acceptable under our statutes.

Typically, these practitioners are contacted by a board attorney or medical investigator and quickly modify their ad and cease advertising in an improper manner. The rule, however, is that the advertising issue is the tip of the bad practitioner iceberg.

Most cases involving fraudulent, deceptive, or misleading advertising by a licensee of the Kansas State Board of Healing Arts will also involve one or more of the following areas: Overutilization of services; suspect billing practices; alleged free physical examinations; writing off of deductible amounts required by insurance contracts; poor quality, or nonexistent lab testing; and diagnosis and treatment based not on solid, objective criteria, but rather upon length of time third-party payors are willing to reimburse the licensee.

In most cases, practitioners in the State of Kansas and elsewhere are mere puppets being manipulated by interstate corporations who entice greedy or gullible practitioners by promising great wealth with little work.

For many practitioners, this lure of easy money is hard to overcome. For *x* amount of dollars, a practitioner can enter into a contract with one of many interstate corporations and be placed on a track advocating misleading advertising, suspect referrals, alleged free examinations, bogus health fair promotions, contracts giving doctors power of attorney, and the writing off of deductible amounts.

The practitioners can purportedly make a fortune with little or no regard for the welfare of the patient. The Kansas State Board of Healing Arts has no jurisdiction over these interstate corporations which seem to be the root of the problem.

The above-mentioned interstate corporations are heavily bankrolled and their legal representatives seem to understand the Federal-State system well enough to keep their clients away from State disciplinary proceedings without subjecting them to Federal contracts.

The Kansas State Board of Healing Arts, along with the medical boards in sister States, attempts to discipline its licensees involved with these interstate corporations by a case-by-case, doctor-by-doctor approach.

However, it makes more sense in protecting the public, whether this be in Kansas or anywhere else in the United States, to define the jurisdiction in these areas and obtain Federal assistance in the policing of the interstate corporations themselves.

As competition in the medical field has continued to increase, it appears that so has the ability of physicians to perform a variety of medical procedures for which they receive little or no formal training.

The majority of the doctors advertising these cosmetic-type procedures are being performed by those individuals who commenced their practice in a different specialty altogether. For whatever reasons, these doctors have found it necessary to enhance and enrich their financial picture by performing procedures for which they have little training and heavily rely upon advertising to attract patients.

The advertisements for the exodermology process as well as other health care procedures obviously come from national marketing organizations which, for a fee, provide these advertisements to subscribing doctors. These advertisements are only a small proportion of the canned advertisements being provided by national marketing firms.

Our office has numerous copies of advertisements which have been prepared by such marketing firms. In providing these advertisements to the individual doctors, absolutely no research or concern is done by the marketing firm to ensure that the doctor who pays for these ads is competent and qualified to perform the procedures advertised.

Rather, the sole criteria seems to be the willingness of the doctor to pay for these marketing services rather than the efficacy of the procedure itself or the ability of the individual practitioner to perform them.

Mr. Chairman, I am sorry I ran over 5 minutes. I am willing, as well as my general counsel, to yield to any questions.

Chairman Wyden. We will have some in just a moment.

[Mr. Gannon's attachment to testimony may be found in the appendix.]

Chairman Wyden. Does your counsel desire to say anything else at this point?

Mr. Buening. Mr. Chairman, no; I have no comments at this time.

Chairman Wyden. Dr. Johnston, welcome, and I take special pleasure in having you and Mr. Ulwelling, our two friends, and people whom I have always enjoyed working with. We will put your prepared remarks into the record in their entirety, and if you all could summarize your views in the interest of time, that would be very helpful.

TESTIMONY OF DR. HUGH B. JOHNSTON, CHAIRMAN, OREGON BOARD OF MEDICAL EXAMINERS, ACCOMPANIED BY JOHN ULWELLING, EXECUTIVE DIRECTOR

Dr. JOHNSTON. I am Hugh Johnston, and I summarized my history and personal experience in peer review, not because it is particularly unique, but merely to show the difficulties a physician would have in this United States in doing peer review in the medical care area.

I know the subcommittee is concentrating on concerns regarding cosmetic surgery, but I feel that the issue is broader than just cosmetic surgery. I feel the issue of who controls the activities of health professionals—should it be left to the consuming public with the knowledge that they can gain from the advertising media, or should it be left to health professionals via regulation?

I feel that a combination of both competition and regulation is necessary. I feel the public is knowledgeable about relative costs, philosophies, insurance plans. They can even look up credentials.

However, the public doesn't really understand, oftentimes, to differentiate between different medical illnesses and claims on various treatment that is promulgated by media advertising. Physicians like myself are increasingly frustrated and frightened in working with the peer review area.

We feel that this is a professional obligation to do peer review. We think it is educational for us and also helps the public. But in the last few years, physicians are less likely to participate, and when they do participate, they are less candid.

They fear the potential liabilities from an antitrust suit generated in the atmosphere of the Federal Trade Commission. There is the possibility of promoting unwarranted medical malpractice suits, defamation suits, antagonism of colleagues even exists there.

But despite that, we probably would go ahead, but considering treble damages, and our malpractice insurance companies will not cover them. When I was a member of the Lane County Medical Society, as its president, I was on the Professional Standards Committee. That group took on all complaints from the public, which I would refer onto the Board of Medical Examiners.

We worked with physicians through gentle persuasion. We often improved communications with patients. But we disbanded the committee because of the liability insurance. We could not get it at all in the present climate.

We also feared the costs that we would generate to the society and its members, trying to work with the Federal Trade Commission in the investigation. When I was president of the Oregon Medical Association, we had a Peer Review Committee, and a Fee Review Committee. The Peer Review Committee still exists. We do, at the Board of Medical Examiners, use that State Medical Examiners' Committee to occasionally look up certain technical areas.

But it doesn't really refer too many cases to the board. It isn't as active as it used to be. This is exemplified by the fact that in the whole 4 years, we have not received one complaint from them to investigate.

The Fee Review Committee has now been disbanded. It did exist as a public service for individuals as well as insurance companies when they questioned an outrageous and excessive fee. We would pressure the physician after seeing if it was several standard deviations away from what the group did. We disbanded because of the actions of the Federal Trade Commission in regard to the AMA.

We tried to work with the Federal Trade Commission at that time. We said, OK, tell us what we can do. We tried to set up rules on how the committee should process and function these fee complaints. After several years of trying to work with that, we judged the issue was too risky to continue to do this public service.

Currently I am chairman of the Board of Medical Examiners in the State of Oregon. We pride ourselves on being on the cutting edge of discipline. But in the competition-only atmosphere, we do not involve ourselves in fee problems or issues of advertising.

The board does have a doctor's title law, which will help us identify chiropractors, M.D.'s, D.O.'s, whatever. We do go after some people who have excessively charged, but we work through—where they are grossly overutilizing also, and that of course, is a violation of the Practice Act.

We just recently promulgated a rule stating that physicians cannot label themselves as board-certified by a specialty board unless that board is recognized by the American Board of Medical Specialties.

Nevertheless, despite these activities, and they are meager, we are still restrained from restricting experts, so-called, the groups that you have heard about, with the franchise weekend wonders of education. They are procedural panaceas who have no credentials going around doing these things.

The board did take a physician out who did face peels. He left the post-operative care to an untrained person in the hotel room, and the patient died from diabetic acidosis.

Currently, there is a general practitioner who drives 100 miles or more from another small community in southern Oregon to advertise his face peel. He is a franchised doctor. He takes people from my community down to his little town and does these procedures on an outpatient basis.

I can do nothing with that man at this time. I have to wait around until he kills somebody. My own personal experience is that there are a number of things that should be done, either by this committee or others. These are my own views and not the views of the board, or of either Medical Associations that I belong to.

I think physicians' offices, emergency care centers, should be required to be accredited by the Joint Commission or some other group of that sort, and public statements about board certification be restricted to those approved of by the American Board of Medical Specialties.

Some other States, I gather, are doing that, too.

Three, it should be required that individuals who do medical practice procedures in the office setting have privileges to do the same procedure in their local hospitals. If you can't be registered to do hemorrhoid procedures in your local hospitals, you shouldn't be doing them.

There are difficulties, I recognize, with this. It does border on antitrust. You have to have credentialing for people not connected with the hospital. You have to have training, and I am not sure whether this should be done or restricted through payment restrictions, through Medicare, or professional regulation.

But certainly, credentialing needs to be enforced. There is time to force in some way the FTC to address the issue of allowing peer review by medical societies. We would prefer to please our brethren. The national bodies of different specialty groups would like to list standards of care. It would be educational to the public and helpful to the physicians.

But they are restrained from doing so. As it stands now, somebody could advertise and make a claim in advertising, and no one dare refute it at the State or local levels, because this would be antitrust.

Five, I feel it is necessary to make the commitment to regulate advertising in the medical field. It should be not buyer beware when you are dealing with professionals. I would eliminate personal testimonials, unprofessional claims, statements that encourage the use of procedures that are not always necessary.

In other words, I would try to have people informed and not promote it. Now, I am aware that this group is working on cosmetic surgery, but I think there are other issues coming down the line.

We have started in our State already having difficulties with laser experts who have taken a weekend course and want to do other—there are other techniques coming along. These can be appropriately used by well-trained people, but they can be abused by ill-trained people.

The public needs assistance in this area in information. The professionals need peer review methods to deal with buccaneer physicians. I believe the FTC, in its haste to do away with the good old boys' anti-competitive network, has gone too far and has left the public bare to misinformation and misused technology.

In other words, snake oil prevails. There are many physicians who serve on licensing bodies like myself, credential committees and other peer review groups who are willing to perform their professional obligation. But we certainly need help in working out guidelines and a methodology to accomplish this.

Thank you.

[Dr. Johnston's statement may be found in the appendix.]

Chairman Wyden. Doctor, thank you.

Both of you have been excellent in every respect. We have a lot of members here today, so I think for our first round, we will have each member begin with 10 minutes.

Let me try to start and see if I can get a few things out on the record. We have before us on this first panel two of the State regulatory boards. You are the State boards and not professional societies, representing both Kansas and Oregon; is that correct?

Would it be fair to say, with respect to your two States, that the Federal Trade Commission's approach to antitrust issues, for example, has hampered your efforts, in your view, to try to protect the public at the State level?

Dr. Johnston.

Dr. Johnston. I don't think there is any question of that. A lot of areas we do not go into. We have been advised by the Attorney General's Office in the State of Oregon to not work in the advertising area because of the difficulties that we would create with the Federal Trade Commission.

Chairman WYDEN. Mr. Gannon.

Mr. GANNON. I would concur with the doctor.

Chairman WYDEN. Mr. Gannon, you mentioned on this point, we would want to refer to your counsel specifically on it. You mentioned several specific decisions that had come from the Federal Trade Commission that went to this point, that the agency is making your life more difficult in terms of protecting consumers.

Mr. Buening, I am a lawyer, not a very good one, but if you could take us perhaps through some of those decisions, and in particular, how it hampers your efforts at the State level, I think that would be helpful.

Mr. BUENING. Certainly, Mr. Chairman. Just as a brief background, our board was created in much of its present constitution in 1957, by our legislature when it consolidated medical, osteopathic, and chiropractic boards into an unusual board. We are a composite board that comprises those three professions, as well as others.

The cases that I am aware of originally came down out of the Supreme Court and dealt mainly with First and Fourteenth Amendment violations in restricting freedom of speech insofar as any State statutes that might restrict advertising by professionals.

The primary case, I think probably, in our area that we are dealing with today, is the AMA case in 1979, brought by the Federal Trade Commission. It specified that there could not be any restrictions on fees or other advertising of an untruthful or deceptive nature and controlled by an AMA professional society.

In the State of Kansas in 1979, we had a case called *Bolton* v. *Kansas State Board of Healing Arts,* which had to do with the present statutes that we then had with regard to advertising by professionals. I have provided to your staff a brief outline, actually just copies of the various statutes and the testimony that has—from our legislative research that led to the changes in our statutes on advertising since 1957.

It started with such things as—could not use flamboyant or extravagant statements, that kind of thing. In 1983, as Mr. Gannon referred to in his statement, the Kansas Legislature adopted a standard that was basically then universal, I think, and that is false, fraudulent, or deceptive advertising that was brought about because of the 1979 decision in Kansas that said, our present statutes were inadequate and unconstitutional, and therefore, this was actually submitted by the Kansas Medical Society, because the Board of Healing Arts at that time had gone through 4 years of not enforcing any restraints on advertising whatsoever, because of the unconstitutionality of the statute.

In that, I would like to quote the testimony of the Kansas Medical Society provided in 1983:

"There have been long successions of Supreme Court decisions that are administrative interpretations by the FTC which make the standard of false and fraudulent applicable across the country."

So, that has led us to where we are on false and deceptive. We have kept up, as I said, in our educational, kept up with a recent case of about a year ago, Massachusetts Board of Registration in

Optometry, that was reported by the FTC Complaints and Orders, "Contrary to the Board's assertions, the FTC has jurisdiction over State boards such as the Massachusetts Optometry Board, members were capable of conspiring with each other to suppress competition in violation of the Sherman Act."

These decisions and a long succession are basically the concerns that are in our mind in any case involving advertising.

Chairman WYDEN. One of the things that I am particularly concerned about is that in health care, you see a trend toward interstate activity and interstate corporate activity, and Dr. Johnston mentioned the tragedy we had in Oregon with the acid peel case. I gather that was an interstate operation.

I would just like to have for the record, do you, Mr. Gannon, and you, Dr. Johnston, feel that this is one area where the Federal Government is going to have to do more, simply because the States don't have the tools to tackle these fast-growing interstate operations.

Mr. Gannon.

Mr. GANNON. Yes, Mr. Chairman. I think there is no other option. We have to have assistance from the Federal Government. The States, we do not have the funding. We don't have the jurisdiction, and we, quite frankly, don't have the expertise to check into these interstate corporations.

Chairman WYDEN. Dr. Johnston.

Dr. JOHNSTON. I would agree. We could do things limited at the State level, but to really get at the heart of it, you would have to go national with a national firm.

Chairman WYDEN. One other area where I take very great exception with the approach of the Federal Trade Commission is this question of how advertising relates to the quality of care. Now, it is quite clear that with respect to quality of health care in this country, that that is not the province of the Federal Trade Commission.

They are not in the business of regulating the quality of medical care. But it is my view that the two are very much related, because if you have false and deceptive advertising, consumers in this country are not going to get the information they need to make informed choices, and, in effect, go out in the marketplace and use marketplace forces to push for better quality of care.

Mr. Gannon, do you share that view?

Mr. GANNON. Yes; I do, Mr. Chairman. I am trying to recall some of the testimony by the Federal Trade Commission I was made privy to, and quite frankly, I haven't had a chance to pick it out. But I think there were some comments in there, perhaps—I can't find it now. Perhaps, Doctor, if you would like to respond, maybe I can find that specifically.

Dr. JOHNSTON. As a physician on a Board of Medical Examiners, we are concerned with the quality of care and have some expertise in deciding on that. But if we try to move against somebody who is falsely advertising, and it is difficult to do that, admittedly, there is a place for face peel in legitimate plastic surgery care. So, you can't say no more face peels in the United States. What you can—so that you have a little difficulty trying to separate that out.

But indeed, as it stands now, if one tries to move against this particular arena, there is always the FTC standing there telling you not to.

Chairman **WYDEN**. Maybe, John, you want to touch on this, but with respect to this relationship between advertising and quality of care, would you share my view that deceptive advertising will have an effect on people's ability to get quality of care?

Mr. **ULWELLING**. Yes; I certainly would, Representative Wyden. I think the point is a good one. I think the best thing that could happen immediately is for the FTC to give the medical boards a green light to move into this area.

As you know, I have served as the executive director for the Oregon Board for 11.5 years. We do not get into this area, because every time we do, and I think this is virtually true for every medical board in the country, there are attorneys advising them that the FTC attorneys will be down your neck in a minute and with a lawsuit.

The proposed rule that Dr. Johnston referred to earlier, requiring physicians, if they are going to be board-certified, that they be board-certified by the American Board for Medical Specialties. We spent weeks reviewing that with our attorney to see if we could even go into that area.

Fortunately, they have said yes; please do.

Chairman **WYDEN**. I am right on my time limit. Let me ask one more. We will have a second round for all the members.

Gentlemen, would you say that the number of complaints is increasing that you see in the medical area and in the cosmetic surgery area, specifically? Do you think that the number of complaints that relates to advertising and the issues we are talking about is increasing.

Dr. **JOHNSTON**. I would say that the number of complaints in general are increasing, and they are also increasing in the cosmetic field.

Mr. **GANNON**. Kansas would agree with that.

Chairman **WYDEN**. Let me recognize my colleagues. In fact, before we do, let me just recognize our friend, who happens to be my mother's Congressman. If he would like to make any opening statement, we would recognize our colleague, Mr. Campbell, for an opening statement, and then I would like to recognize Mr. Hancock.

Would the gentleman like to make any statement?

Mr. **CAMPBELL**. In the interest of time, I will congratulate you for holding these hearings, and I have enjoyed the testimony I heard so far. I look forward to your vigilance in protecting the rights of consumers.

Chairman **WYDEN**. We look forward to having our colleague who is an expert in this area, and look forward to working with him in this area.

The gentleman from Missouri.

Mr. **HANCOCK**. Mr. Gannon, how large is your enforcement staff? Do you have an enforcement staff in your organization?

Mr. **GANNON**. Mr. Hancock, currently, we have 16 FTE's. The Legislature just allowed me to bring our four additional personnel in as of January 1.

Mr. HANCOCK. Are these legislative personnel?

Mr. GANNON. I have three investigators. I intend to employ one other. We do have licensing as well as disciplinary activities under the jurisdiction of the board. I do have general counsel. I have a prosecuting attorney, and I am also going to be bringing another attorney on board.

Mr. HANCOCK. But you operate under the State Attorney General's Office; is that correct?

Mr. GANNON. No, sir; we have the luxury, unlike many of our sister States, to undertake our own investigations and do our prosecuting.

Mr. BUENING. If I could respond to that? In 1984, the legislature authorized both a disciplinary counsel and a general counsel to be employed by the board. I was talking to Mr. Clark, the executive director of the Missouri Board, on Friday, and he indicated that that is quite different in the State of Missouri. They utilize some private counsel, but they utilize primarily based upon your legislature in Missouri, the Attorney General's Office, which is really rather common throughout the Nation.

I think his total office staff is going to be like 28, as opposed to ours, which will be 20 starting July 1. But that is total administrative, clerical, the whole thing.

Mr. HANCOCK. Dr. Johnston, has your organization had any direct contact with the FTC?

Dr. JOHNSTON. No, sir; we try to stay away from the FTC.

Mr. HANCOCK. In other words, my follow-up question on what the subject of the discussions were is kind of moot, isn't it?

Chairman WYDEN. I thank my colleague.

The gentleman from California.

Mr. CAMPBELL. Well, if you don't look for them, they will look for you.

I thank the chairman, and I appreciate the honor to represent his mother. He really put me on the spot. My God, if I misbehave, I will lose a constituent.

I would like to address a couple of questions dealing with the State control issue and the Federal control issue, so, I am directing these to Mr. Buening, but the other gentlemen are invited to respond.

Are you familiar with a case called *MEDCAL*, dealing with the antitrust exemption for State action?

Mr. BUENING. Yes.

Mr. CAMPBELL. And are you familiar with *Bates* v. *Arizona*?

Mr. BUENING. Yes.

Mr. CAMPBELL. They established the principle that a State could, if it chooses to, remove an entire area out of Federal antitrust jurisdiction; is that correct?

Mr. BUENING. Yes.

Mr. CAMPBELL. Then why, may I ask, in your State of Kansas, or perhaps in Dr. Johnston's State of Oregon, have you not sought the relief appropriate under *MEDCAL* or *Bates* by going to the Legislature and saying, we would like you, please, to take this out of Federal antitrust jurisdiction?

Mr. BUENING. That is a very good question. The answer, as I understand it to be, is that court cases, in addition to the FTC cases, the court cases which have come down, and I have referred to, have basically stated that the States may not unconstitutionally deprive people of First and Fourteenth Amendment rights, free speech and due process.

In that regard, the standards have been set, not necessarily simply by FTC, but also by the United States Supreme Court, that false, fraudulent, deceptive, and misleading are the standards that are constitutionally permitted.

If I might quote again from the Massachusetts Board of Registration in Optometry, another paragraph I didn't state. It says, "Under certain circumstances, a State may insulate a regulatory board from Federal antitrust scrutiny. However, because Massachusetts law specifically bans State boards from prohibiting truthful advertising, State action immunity did not apply."

The United States Supreme Court says, States, you must allow truthful advertising, and, therefore, whenever the State does something that the FTC says, well, we think that is truthful, and you have restrained trade, we are caught between the court system and the FTC.

Mr. **Campbell**. Are you today here advocating an Amendment to the Constitution of the United States?

Mr. **Buening**. No, sir.

Mr. **Campbell**. Then let's assume that the First and Fourteenth Amendment will not be changed by my actions today or your actions today. Why do you not go for the ability existing in the law subject to the Constitution to take the entire field away from the Federal Trade Commission by action of the Kansas Legislature?

Mr. **Buening**. Number one, I don't think we can control the interstate corporations. What we have in today's society and in the marketplace today is we have advertisements flowing into the State of Kansas that are—these doctors are not preparing. They may indeed be running them, and placing them, and paying for the actual ad themselves, but they are being prepared by some market or advertiser.

Mr. **Campbell**. Is it your opinion as an attorney that Kansas lacks jurisdiction to regulate advertising that goes on the air waves in the State of Kansas or advertising that appears in print in Kansas?

Mr. **Buening**. The State Board of Healing Arts only has the ability to regulate those who license that.

Mr. **Campbell**. The State legislature. The point to which I am getting, which I am afraid is painfully obvious, is there is another forum to which I suggest these complaints are appropriately brought under your scheme of federalism and antitrust.

If you were to take the concerns you have to the Kansas Legislature, and if Dr. Johnston and Mr. Ulwelling would do the same in Oregon, and if they were to pass a law saying that hence forward, we shall have supervision of practices in the medical advertising areas to be handled by our State board, preempting the Federal scheme, subject only to the Constitution, as I read *MEDCAL* and *Bates,* those State legislatures would have the right to do so.

So, I am asking you if you disagree, please let me hear. I am more than happy to take the correction, and if you don't, then I am asking why you haven't sought that relief.

Mr. ULWELLING. I think that we will explore your suggestion with our attorney. You need to know that in our statute, we already have language that says, "Making false or misleading statements regarding skill, or the efficacy, or treatment, or the value of the medicine, treatment of remedy prescribed or administered by the licensee or at the direction of the licensee in the treatment of any disease or other condition of the human body or mind."

We have statutory language. The thing that concerns our attorney, and I am speaking for him, is that when you get the Texas Board of Chiropractic Examiners, who propose what, 15 administrative rules, some of them regarding fraudulent and deceptive advertising which we think is straight right out of our Practice Act, and the FTC is recommending that they cease and desist on those regulations, that more to the point, you have the Oklahoma Medical Board trying to address fraud and deception and the FTC staff recommending—the FTC Commission didn't go along——

Mr. CAMPBELL. You are telling me a problem with your present State law. That could be preempted the way Arizona did on advertising, by taking the matter entirely within their own State. So, it may well be that under existing law in Oregon, there is an opportunity for the FTC to still play a role, and I grant that.

I am only asking you to give some consideration——

Mr. ULWELLING. We will explore that. We are not advocating going back to the old days. We are advocating—if the FTC would say in the area of fraud and deception, that the medical boards can go ahead and proceed——

Mr. CAMPBELL. Let me deal with just that. A question to Dr. Johnston. You say that you don't want to go back to the old days. I am not sure. Did you think that *AMA* v. *FTC* was wisely decided? Do you think that the laws should have provided to the medical profession?

Dr. JOHNSTON. I would have to say that since my tour on the Board of Medical Examiners, at the time I did not agree with that view, but I would have to say now that it was probably appropriate to restrict the AMA to some degree.

Mr. CAMPBELL. To that degree, would it include price fixing agreements between doctors?

Dr. JOHNSTON. That is one of the problems. When our Fee Committee, as I was talking about, we were told that if somebody was charging seven times what most people would charge in that particular area, we couldn't go after them and tell them, no; you can't do that because that is setting the fee. It is saying what the real fee is, and so, we were restricted in that particular area, so we couldn't do anything.

Mr. CAMPBELL. My question was whether you think that is a good idea or not.

Dr. JOHNSTON. I wish I could go back with some guidelines. I think there is a balance here, and I think we swung too far away from allowing any regulatory capacity.

Mr. CAMPBELL. Please tell me if this is not a correct statement, but it would be your judgment that the interpretation of *AMA* v. *FTC* should allow some ability for groups such as yours to have a role to play in the setting of prices for medical procedures?

Dr. **Johnston**. Certainly the State regulatory board. I would like to answer your previous question, too. There are some—for instance, the individual who comes to my community with his franchised face peel only lives 10 miles from the California border. He can go over into California and do it from the office out of there. So, there is a State line issue where we cannot deal with his practice in the State of California.

Mr. **Campbell**. Indeed, I think that is a very, very good point. To the extent that person comes over the line into Oregon, you can deal with his or her practices in Oregon, and I would ask you to trust me and my fellow Californians to handle his or her practices on my side of the line.

Dr. **Johnston**. I would trust California, but there are other States around Oregon.

Mr. **Campbell**. It might come to a fundamental difference who we trust in the Federal scheme, which we cannot resolve today.

One last question. The description is an interesting one that I have heard from you gentlemen today. There are some who say we need more Federal regulation because of interstate problems.

Then I hear the point of view that FTC should stay the heck out—I don't think anyone used the phrase, "heck", so excuse me—out of our line of work. This is something that should be done by peer review, by professional organizations within the States. I have a little bit of a sense of ambivalence in the proper role for the Federal Government.

Allow me to make the following observation: You would like the Federal Trade Commission to assist the work established by the peer review committees. Perhaps, Dr. Johnston would say that would be in peer review of fees. Perhaps, Mr. Gannon would say deceptive advertising. But you wouldn't like the Federal Trade Commission, in their assistance, in giving our resources to assist, you would not like to carry with that any package of what is false, misleading, deceptive advertising.

That is a fair summary of your view?

Dr. **Johnston**. That is correct.

Mr. **Campbell**. Then I have just a final question, and it is a very open-ended one to Dr. Johnston and to Mr. Gannon. Could you give me one example of the sort of conduct by physicians or would-be physicians that you would like to sanction, but are prevented from doing so because of the Federal Trade Commission?

I would like one example, please.

Dr. **Johnston**. I think on the whole area of advertising, I could pick up my own telephone book in Eugene—coming through San Francisco last night, the advertising in the San Francisco paper, 16,000 procedures, no complications. I don't think you can do 16,000 of anything without some problems. So, the whole area of truthfulness in advertising is not being approached.

I don't think any group is approaching it because of the FTC at this time. I know we are not dealing with the fees.

Chairman **Wyden**. Would the gentleman yield? I want to ask one question on that. Can't you claim anything you want in the Yellow Pages, and absent there being a specific complaint, it gets to stand forever?

Mr. **Ulwelling**. That is correct.

Chairman WYDEN. I appreciate the gentleman yielding.

Dr. JOHNSTON. I have a whole list taken out of what is in my little old Eugene, OR——

Mr. CAMPBELL. I would never refer to Eugene as little or old. But just to follow your point, the example that you give me of where you would like to regulate, but are prevented from doing so, is an advertisement in the Yellow Pages which you might have seen in Eugene, and you happened to see in California, but you might have seen in Eugene, saying 16,000 procedures, no accidents.

Dr. JOHNSTON. Yes.

Mr. CAMPBELL. Saying 16,000 procedures, no accidents, no mistakes?

Dr. JOHNSTON. Yes; I don't think that is true.

Mr. CAMPBELL. I take your point, and could you refer me to the FTC opinion that—or letter or comment—wherein the FTC told you that you could not regulate that?

Dr. JOHNSTON. I don't have an opinion that says I can't go after that kind of person. I have a whole series of laws that have been accumulating over the last 10 or 15 years that tell me stay out of advertising.

That is what I have been told.

They didn't say, "Don't go after the 16,000."

Mr. CAMPBELL. I will turn the question to Mr. Gannon. I am asking for a specific instance where you would like to regulate and the FTC specifically told you not to.

Dr. Johnston, I think you are describing a chill, but you didn't give me a specific where the FTC ordered you could not.

Dr. JOHNSTON. The FTC has not communicated directly. The AMA action, they have investigated the Maine Medical Association, the Texas Board of Chiropractors, the Oklahoma Board of Medical Examiners.

These are all things we keep track of through the Federation of Medical States.

Mr. CAMPBELL. In any instance, did the FTC prohibit a State from taking action against a false advertisement?

Dr. JOHNSTON. In the Oklahoma issue, I think they said something to the effect that you cannot keep a physician who says he is a specialist from calling himself a specialist even though he is not accredited by a reliable board. That is the problem as far as I see it.

Mr. CAMPBELL. As to how you interpret false and how another agency might?

Mr. GANNON. In response to your question, the Kansas State Board of Healing Arts, to the best of my knowledge, has communicated with the FTC once in the past 5 years, communication with Mr. Buening to my right, in regard to this particular case that you have attached to my testimony.

Frankly, maybe Mr. Buening would like to speak to this, but the phone calls were primarily an inquiry on what we were doing.

Of course, whether you have the Federal Government calling you, you wonder what is taking place.

If I might be allowed, I will perhaps bring to your attention this particular case we are involved in litigation now with the doctors.

Mr. CAMPBELL. It is the chairman's prerogative to give additional time.

If I could direct my question one way—is it a fair statement that you never received any instruction order from the FTC that your Board of Healing Arts in Kansas could not proceed in a particular way?

Mr. GANNON. That is correct.

Mr. CAMPBELL. Thank you, sir.

Chairman WYDEN. Go ahead and tell us about the case.

Mr. GANNON. Thank you, Mr. Chairman.

What you have attached to my testimony are pictures of patients. Quite frankly, we don't know whose patients these are. This particular advertisement is the one that the Kansas State Board of Healing Arts found to be terribly offensive.

It involves the exodermology process: you have a patient before and after.

What the board found to be terribly offensive is the "Labeled Miracles in Just 8 Days Are Our Stock in Trade."

If you had phenol acid applied to your face, according to our experts, you would look like raw hamburger.

We did censor the doctors. They have ceased this advertisement.

However, the most recent advertisements are these. This one doesn't say anything about a miracle in 8 days, but it says, "We eliminate lines, pock marks, blemishes, and spots with our nonsurgical process."

We have had a long discussion about this patient in my office. We are not certain if it is the same woman. This one looks as if she has been on a 2-week drunk. She hasn't washed her hair and she looks rough.

There is a big difference here, members of the committee. We are afraid that the board cannot take action with regard to this case.

Chairman WYDEN. In this instance, we are talking about an interstate corporation, aren't we?

Mr. GANNON. Yes.

Keep in mind we have subpoenaed patients' records here, but I am confident there is no way that the doctors involved can provide them.

I am confident they are like these—they don't know the patients, have never seen them. They can't give you any case history.

Our surgeon feels this woman may have undergone plastic surgery.

Look at this woman here. Look at the size of her nose. It has been diminished. You would have to pour a lot of acid on somebody's nose to reduce it to this size, but there may also be some trick photography involved.

Mr. CAMPBELL. To follow up, these are interstate companies. I take it, however, there was a practitioner in Kansas who was advertising in this manner?

Mr. GANNON. There were two practitioners, a father and son team, who were advertising with this material.

Mr. CAMPBELL. You sought to sanction those individuals within Kansas?

Mr. GANNON. That is correct.

Mr. Campbell. To what extent did the fact that it was an interstate operation inhibit you from bringing sanctions on those two residents in Kansas?

Mr. Gannon. The reason we provided disciplinary action against these doctors is because of the 8-day issue. This material our investigation revealed had been provided to these doctors.

We are not certain if they came from an individual in California or an individual in Florida.

We think, perhaps, it is the same individual. It is very difficult to deal in that investigative arena with our resources.

It has also been brought to our attention now that these doctors have the franchise for this exodermology system, now that they are marketing that in the interstate arena.

Chairman **Wyden.** Isn't it a fact that you or another small state like Oregon simply don't have the resources to take on a major interstate case like this? Even if we were to wade through the legal arcania, most States wouldn't have—except maybe New York or California—but the vast bulk of the States in this country wouldn't have the resources to take on these interstate cases and the FTC isn't doing it today?

Mr. Gannon. That is correct.

Our operating budget is $1,300,000. We don't have the resources available to take on this type of activity.

I think this is what the Founding Fathers intended. The States, working in concert with the Federal Government, will address these types of problems?

Mr. Buening. Another problem, all States, I think—in Kansas, we have to prove our case by substantial evidence in an administrative proceeding, whether it is false, fraudulent, deceptive, or misleading, we have the burden of proof to show that there is substantial evidence to show that a violation of our Healing Arts Act has occurred.

In these cases, advertising before and after pictures are being provided by out-of-state corporations, people the doctors don't know—are those false photos?

We can't prove that.

Are they deceptive? I would have to see the patient before and after. It is very difficult for us to get the amount of proof necessary to show substantial evidence that a violation has actually occurred.

Mr. Ulwelling. We have very effective use of subpoena power in Oregon.

Once outside of the State, then we are totally dependent upon the agency in another State to release information. It would be very difficult to get information.

Chairman **Wyden.** I gather that the people who you have sanctioned in Kansas and in Oregon, you have evidence that they are trying to now move out of State as well?

Mr. Gannon. That is correct. It is really sad.

Mr. Ulwelling. In Oregon, no; he has given up the practice and has left.

Chairman **Wyden.** Let me try to pick up on a point you made, Mr. Ulwelling, with respect to not wanting to go back to the old days.

I think that is a very important point, because I want to say again—I did in my opening statement—that I think competition has an important role to play in American health care. I think that responsible advertising arms citizens with information so they can make intelligent choices.

Do I understand you two, Mr. Gannon and Dr. Johnston, you essentially agree with that view and your position is that the FTC has gone too far. That in the name of competition and getting people information, they have essentially gone too far, and now we have to take steps so the States can move to protect their citizens?

Mr. ULWELLING. That is correct.

Mr. GANNON. Yes.

Chairman WYDEN. Let me ask you on this point of false and deceptive advertising in particular, what it is that the States would really like in this area, and let's use cosmetic surgery specifically as our example.

The first thing I gather from your testimony is that what you all essentially would like are some guidelines.

You don't want prescriptive mandatory kinds of approaches, but essentially, guidelines as to how to proceed, is that right, Mr. Gannon?

Mr. GANNON. We need guidelines, but frankly I think we perhaps need more than that.

I am going back to this particular case. When I am thinking about individuals promoting this exodermology floating from State to State, even the guidelines would be enough.

Chairman WYDEN. You would like the FTC to come out with some standards in this area?

Mr. GANNON. I think that is correct. Someone has to have jurisdiction over the multi-States. We need help.

Mr. ULWELLING. We would like the guidelines to go discipline, and we think the national organizations will give standards that will allow us guidelines.

Chairman WYDEN. It is my view that we already know enough, and we saw in Mr. Oliver's opening statement that they would start to study these things at this point.

You think we know enough on these before-and-after ads?

Mr. GANNON. In my mind; yes.

Mr. ULWELLING. Yes.

Chairman WYDEN. With respect to certification, something that we heard about in our last hearing that, in effect, practitioners hold themselves out to be something other than what they are, that they are all doctors, they have a State medical license, but they have a specialty in a particular area. Do you feel that there ought to be some standards in that area, Mr. Gannon?

Mr. GANNON. Yes, sir.

This is a case where we took disciplinary action against a doctor, a board-certified orthopod, in his mind. He was involved with an organization out of Las Vegas, NV.

I have a copy of his stationery here. It is extremely impressive.

I doubt there is anyone on the committee that could compete against it. Not only is he board certified of orthopedics in his mind, but he is the dean of his own law school.

The State of Kansas took disciplinary action against him, but it wasn't as far as medicine is concerned. It is just that we couldn't stomach the fact that he was dean of his own law school.

I might comment with regard to this Las Vegas organization that they also have a habit of giving out Ph.D.'s and a recent one was given to a young woman that provided the typing to this organization.

We find that a little offensive.

Chairman **Wyden**. So, on the certification issue, you would like to see standards?

Mr. **Ulwelling**. We would advocate doing what we propose to do effective in July. If a physician is going to be held out to be board certified, it would have to be approved by the American Board of Medical Specialties. No one else could use board certified, period.

Chairman **Wyden**. Regarding substantiation of some of the claims being made, I think some of what is being offered again goes way beyond informing, which I think is what advertising is about. But this is just huckstering by making these wild claims without substantiation.

Is it your view, Mr. Gannon, that there should be standards with respect to substantiation?

Mr. **Gannon**. Yes, sir.

Chairman **Wyden**. Mr. Ulwelling.

Mr. **Ulwelling**. Yes.

Chairman **Wyden**. One last point.

I take the view now that because of policies that have evolved over the last 10 years, it is more difficult today for people to get responsible, solid information on which to make choices—to distinguish between good doctors and bad.

Mr. Ulwelling, what do you think of that?

Mr. **Ulwelling**. I think that is correct.

Dr. **Johnston**. Good doctors and bad doctors. I would say some doctors are good at certain things, but they aren't good at everything they think they are doing.

Chairman **Wyden**. Mr. Gannon, with respect to people making intelligent, informed choices, which is what the whole thrust of what we want to be doing in Federal policy is about, have some of these policies made it more confusing and hard to do that?

Mr. **Gannon**. Thinking back to my old senate district and the people I represent, frankly the mindset, which was an Ararian district, if you were a doctor, you were up here, and really no matter what the doctor told you, you were going to believe him and do it.

We are seeing a lot of people injured with that type of activity.

We have some poor practitioners out there. I am proud of the State of Kansas and our aggressiveness. The State of Oregon is aggressive, too.

We try to be proactive instead of reacting to situations. We just hate to see people harmed, and we have to wait until somebody gets hurt before we can take action. It is a shame.

Chairman **Wyden**. I think that really sums it up very well.

Let me see whether my colleagues have any additional questions.

We are pleased that our friend from New York, Mr. Engel, has joined us.

I will be happy to recognize him for any questions he would care to ask at this time.

Mr. ENGEL. Let me first say, Mr. Chairman, that I would like to apologize for being late, and I would like to submit my opening statement. I won't bother reading it.

Chairman WYDEN. Without objection, so ordered.

[Mr. Engel's opening statement may be found in the appendix.]

Mr. ENGEL. Dr. Johnston, you say that there has been at least one death in Oregon because of the chemical peel process?

Dr. JOHNSTON. That is right, sir.

Mr. ENGEL. You seem to imply that—and forgive me because you may have covered this—there is nothing you can do about practitioners using this method?

Dr. JOHNSTON. That particular physician, when the patient died and, therefore, we had a complaint, we could then proceed to investigate, but there are other physicians, at least one that I am most familiar with, who is no better trained as far as we can see from his credentials on the surface, who has only just had the weekend course who is offering the same kind of procedures in the same way with practically the same picture ads, and I have been told to sit there and wait for him to do the same thing that his colleague did, and then I can get him.

Mr. ENGEL. So, you actually have to wait for deaths or injuries until you can go after him?

Dr. JOHNSTON. At the present time, unless we go after his advertising schemes, which we have been told not to do.

Mr. ENGEL. It seems common sense would dictate it would be better to set advertising standards.

Dr. JOHNSTON. We would be glad to issue and promulgate rules in this area, but we were told that is not going to be allowed by the FTC.

We haven't issued the rules and then had the Federal Trade Commission go after us for that.

Mr. ENGEL. Could you lead me through this in terms of what has happened in Oregon about the FTC?

It would seem to me that it is rather heavy-handed for them to act the way they act.

Dr. JOHNSTON. We look at the case law across the United States. I look at my own experience in dealing with the FTC and medical societies. We are trying to deal with them and trying to do what we thought was a public service.

Now that I am on the Board of Medical Examiners, I see the same pall that is put over the proceedings by the fact that they are not, though they haven't said directly to us, we see what they do with other regulatory bodies throughout the United States, and we don't need to be the first one on the block to get knocked down, I guess.

Mr. ENGEL. If the FTC took action on its own against some of these deceptive ads, don't you think that would show the way to a State enforcement agency such as your own to set up State efforts?

Dr. JOHNSTON. If they said these certain things are not allowed, standards, if you will, we would promulgate almost the same rules and proceed to do our own investigating and our own taking out of physicians who were doing that.

Mr. **Engel**. We are going to hear from Mr. Oliver in a little while.

Apparently, in his testimony he is going to say that the FTC, in its policies, welcomes and encourages States to take action against these misleading ads and against the dangerous doctors and procedures.

I wonder if you can comment on that.

Do you buy that?

Dr. **Johnston**. I have never received any communication from the FTC encouraging me to go after advertising rules. All I have seen is throughout the United States, as I say, other agencies being disciplined and criticized for doing the same.

We couldn't afford it in the State of Oregon to have our attorneys spend their time defending us for such actions by the FTC. We have other things to do.

Mr. **Engel**. So, in essence, you would say that the FTC has not given you a green light to enforce these standards?

Dr. **Johnston**. To the contrary. We see red lights all over the country.

Mr. **Engel**. One final question.

Mr. Oliver is going to mention that the FTC restraint of trade actions against State boards or medical societies have expressly permitted the rights of these groups to control outrageously deceptive advertising, but in reality, what have been the results of these restraints of trade actions on your ability to control advertising, given the kind of legal counsel your group has been given by your attorneys?

Dr. **Johnston**. Our attorney said don't get involved with it. The FTC will not approve. I have to go by what the State attorney tells me.

Mr. **Campbell**. One follow-up question to Mr. Gannon and Dr. Johnston, so I understand your point about the ads.

These ads that you held up, I take it, all appeared within your State, Kansas, or Oregon, and connected with an individual practitioner offering a service within that State; is that correct?

Mr. **Gannon**. No, Mr. Chairman.

Mr. **Campbell**. Tell me how they occurred.

Mr. **Gannon**. I am under the impression that these have appeared in several States, the same advertising. It just so happens that the doctors who we have censored were practicing and licensed by the State of Kansas.

They are now providing this information, these brochures to a multi-State arena.

I am under the impression it is like a domino effect. You have one individual who may or may not have been a licensed physician who started this, and then he franchised this out to gullible doctors and they, too, provide——

Mr. **Campbell**. I appreciate your answer, but I am not sure it is on the question.

Let me try again. The ads that you see in your job in Kansas that you hold up before our subcommittee carried with them, did they not, the name and address or phone number of a medical practitioner within Kansas or may or may not have been making use of an ad that appeared in Illinois, and Missouri, and so forth?

Mr. Gannon. There is a name of a Kansas association associated with these ads; yes.

Mr. Campbell. With everyone?

Mr. Gannon. Yes.

Dr. Johnston. They are licensed in the State of Oregon to be a general medical officer.

Mr. Campbell. That is my question.

Thank you.

Chairman Wyden. Have you all seen similar kinds of ads to the ones we are talking about?

Dr. Johnston. They are franchised ads. The same ad that would appear in Oregon appears elsewhere. I don't think they get surgery in all several States.

Chairman Wyden. Would any of you like to add anything further?

We will excuse you at this time. I think that the work of the States is a particularly important matter right now, because the Federal Trade Commission has put so much emphasis on State activity. But then, you all come to the Congress, I think it was in the words of you, Mr. Gannon, and tell us that you face the chilling prospect of action against you by the Federal Trade Commission.

That concerns me greatly.

So, we are going to want to work with you in the days ahead.

I can tell you that there are a number of others who feel that there should be some changes in FTC policy.

I want to note for the record that a majority of the FTC rejected the views of the chairman. So, I think there is quite a debate even within the Commission about how to proceed.

We will be working with you closely in the days ahead.

We are going to take a 5-minute break at this time, and in 5 minutes, we will go forward with our hearing.

We thank you all for coming to testify.

[Brief recess.]

Chairman Wyden. Mr. Oliver, we welcome you.

I think I recognize the gentleman on your left as Mr. MacLeod. We welcome you as well

Mr. Oliver. This is Jeffrey Zuckerman.

Chairman Wyden. You were once identified as Mr. Wyden on a magazine, Mr. Zuckerman. I don't know if you recall such an occasion.

I hope your staff found that as entertaining as mine did.

Mr. Zuckerman. I don't recall it, but I find it very flattering.

Chairman Wyden. It caused a great deal of merriment in our office.

Gentlemen, it is the practice of our subcommittee to swear all witnesses.

Mr. Oliver, is it your desire to have your colleagues serve as witnesses or counsel? What is your pleasure in that regard?

Mr. Oliver. Witnesses, I think.

Chairman Wyden. We will just swear you all, and that will take care of it.

Mr. Zuckerman. Could I go by affirmation instead of oath for religious reasons? I have always done it before.

Chairman **Wyden**. Yes; we have not been asked that before, but that would be very appropriate.

[Two witnesses sworn; one affirmed.]

Chairman **Wyden**. Gentlemen, we welcome you. We will make a copy of your prepared remarks a part of the record in their entirety.

Mr. Oliver, if you could summarize your views, that would be very helpful. Before you do, the Chair would like to say that over the years, you and I have had a number of debates on a number of issues, and certainly we both have strong views, and have had, I guess you would say, significant differences of opinion.

But I just want you to know that I feel that at all times, you have been very courteous and considerate to this Member of Congress and to me, that is what the business of making public policy is about.

People have reasonable differences of opinion, but what is important is we have a chance to debate those and pursue them in a civilized fashion, and I appreciate that.

TESTIMONY OF HON. DANIEL OLIVER, CHAIRMAN, FEDERAL TRADE COMMISSION, ACCOMPANIED BY JEFFREY I. ZUCKERMAN, DIRECTOR, BUREAU OF COMPETITION, FTC, AND WILLIAM C. MacLEOD, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FTC

Mr. **Oliver**. Thank you for those very kind remarks. I am pleased to be here. I enjoy discussing the issues with you. I suspect we won't agree on everything, but we will see what happens.

Mr. Chairman and members of the subcommittee, I appreciate this opportunity to discuss the Commission's involvement in advertising by physicians for cosmetic surgery procedures.

As you know, Mr. Chairman, for 15 years, under five presidents, Republican and Democrat, the Federal Trade Commission has followed a consistent policy of law enforcement to preserve competition and consumer choice for the benefit of consumers of health care services.

In particular, the Commission has challenged the suppression by professional groups of truthful, nondeceptive advertising that can help consumers choose among health care providers.

The Commission's work in this area reflects a broad public consensus that attempts by professional self-regulatory groups to restrict truthful, nondeceptive advertising had gone too far.

The U.S. Supreme Court took the first important steps in this area with its decisions in the *Virginia Board of Pharmacy* and *Bates* cases, holding that professionals have a First Amendment right to advertise.

The Commissions' health care antitrust program has had the equally enthusiastic support of Democrats and Republicans—of Democrat Michael Pertschuk, who was Chairman in 1979 when the Commission handed down its decision in the *American Medical Association* case, and Republican James Miller, who was Chairman when the Commission's decision was affirmed by the Supreme Court.

The Commission's efforts have received support from such diverse groups as the Washington Business Group of Health, the United Steelworkers of America, the American Association of Retired Persons, and the American Nurses Association.

Here are some examples of advertising that medical groups have tried to prevent: Advertisements about a low-cost cardiac stress clinic operated by a church group; advertisements by an occupational health clinic informing local employers of its programs to prevent, as well as treat, on-the-job injuries; and, advertisements by doctors in an area with a large elderly and Spanish-speaking population informing consumers that they accept Medicare assignments or speak Spanish.

The Commission's program of challenging restraints like these presents no obstacle to effective regulation of false or deceptive advertising by medical associations, State medical boards, or State attorneys general.

Every Commission order in every advertising-restraint case involving State boards or professional medical associations has explicitly permitted the adoption and enforcement of rules against false or deceptive advertising.

Throughout this same 15-year period, the Commission has initiated hundreds of investigations and filed scores of cases that sought to protect consumers from false or deceptive representations in the promotion of health care products and services.

Many of these actions have involved marketing efforts by medical professionals, including physicians, chiropractors, dentists, hospitals, and clinics. Several have involved cosmetic procedures, such as chemical face peels and hair implants.

Since 1983 alone, the Commission has brought more than 40 cases that sought to bring an end to apparently deceptive advertising of health claims. The Commission's health care program has undoubtedly saved consumers millions of dollars that might otherwise have been wasted on unproven products or services.

With regard to physicians' advertising of cosmetic surgery procedures, we note that these hearings have covered issues ranging from, on the one hand, advertising that may be false or misleading, to, on the other hand, patients who are put at risk by the competence of particular physicians.

These are both important issues, but they should not be confused with each other. False, misleading advertising for cosmetic surgery is, and should be, a matter of concern to all agencies and organizations that have responsibilities for regulating it. This concern is shared by the Federal Trade Commission.

Quality of care and physician competency is also, of course, a very important issue, but it is not an issue that the Federal Trade Commission can, or should, regulate.

The physician's competence and the ultimate safety of a medical procedure are clearly within the purview of the State medical boards. To the extent that advertising by these providers raises deception issues as well, regulators may need to proceed against that advertising.

But advertising regulation is not a substitute for action to assure that practicing physicians meet standards of competence consistent with the need to protect public health and safety.

In its review of cosmetic surgery advertising, Federal Trade Commission staff has been working closely with representatives of the professional societies and certifying boards. Federal Trade Commission staff has also been in contact with the Federation of State Medical Boards, and individual State medical boards across the country, to obtain their views on the extent to which advertising of cosmetic surgery procedures or the competence of physicians to provide such procedures is a problem, what measures they have taken to address that problem, and how we can help in that effort.

Among the issues Federal Trade Commission staff is considering are representations regarding the safety of a particular cosmetic service or procedure, the use of before and after pictures to demonstrate the results one can achieve, and claims regarding the qualifications of the advertiser to perform cosmetic surgery.

It is apparent, however, that almost all of the advertising by cosmetic surgeons takes place at the local level, where two layers of regulation cover the practices we are discussing today.

First, the local medical boards have the jurisdiction and responsibility, as well as the expertise, to act against doctors who promote their services deceptively or who perform these procedures incompetently.

Second, State attorneys general have authority similar to ours to stop false and misleading advertising. I agree with the recommendation of the recent ABA report on the role of the Commission that "when the Commission learns of a questionable advertisement with a principally local effect" it should "refer the matter to the appropriate State and offer to help."

I should note, however, that State medical boards that Federal Trade Commission staff have spoken with have said that consumers generally do not complain to them about cosmetic surgeons' advertising. Typically, the complaints they receive about advertising come from competing doctors or from their professional associations.

The State boards seldom encounter incidents involving deceptive advertising by cosmetic or plastic surgeons, and they report relatively few instances of incompetence in the performance of cosmetic surgery procedures. Where such problems do arise, the boards say they are proceeding with individual disciplinary measures.

Our many cases against advertisers of health claims demonstrate the role that the Commission can play. Should the Commission's ongoing review of advertising identify claims that are false and misleading, we can proceed directly against such advertising where it has interstate effects, and we can also encourage State medical boards and attorneys general to follow up with actions of their own against local practitioners who may be engaged in similar activities in their jurisdiction.

The staff of the subcommittee has advised us that some State medical boards, nonetheless, may feel inhibited in acting to bar deceptive advertising because of the FTC's interest in promoting healthy competition among physicians.

I hope this statement today has made clear that there is no conflict between healthy competition and effective regulation of deception.

The Commission strongly believes that stifling the flow of accurate and truthful information in advertising is anticompetitive and not in the best interests of consumers. However, prohibiting false, misleading, and deceptive advertising promotes the interests of consumers.

The Commission welcomes the opportunity these hearings present to clear up any confusion that may exist concerning the importance of both competition and consumer protection in serving consumers of medical services.

Finally, I want to thank the chairman for giving consideration to the time constraints of my schedule this afternoon, and I will be happy to answer any questions you or members of the subcommittee may have.

[The statement of Daniel Oliver and the dissent of Commissioners Mary L. Azcuenaga and Andrew J. Strenio, Jr., follow:]

TESTIMONY OF

CHAIRMAN DANIEL OLIVER

OF
THE FEDERAL TRADE COMMISSION

Before

HOUSE COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON REGULATION
AND BUSINESS OPPORTUNITIES

Washington, D.C.

May 31, 1989

Mr. Chairman and members of the Subcommittee: My name is Daniel Oliver and I am chairman of the Federal Trade Commission. I appreciate this opportunity to discuss the Commission's involvement in advertising by physicians for cosmetic surgery procedures. The views expressed in this statement are my own and do not necessarily reflect the views of the Commission or any other Commissioner.

At the hearing held by your Subcommittee on April 4, several concerns were raised about the role of the Commission in protecting consumers from deceptive practices and in ensuring that markets operate free of competitive restraints. Today I will address those concerns, and attempt to clarify for you the FTC's goals and initiatives in this area.

I would like to begin by addressing the Commission's competition program as it applies to the health care professions. As you know, Mr. Chairman, for fifteen years, under five presidents, Republican and Democrat, the Federal Trade Commission has followed a consistent policy to preserve competition and consumer choice for the benefit of consumers of health care services. For example, the Commission has halted provider boycotts that threatened to harm consumers: boycotts intended to eliminate HMOs and out-patient clinics; boycotts to obstruct cost-containment programs that save consumers money; and boycotts to coerce hospitals to refuse hospital privileges to podiatrists, certified nurse-midwives, and other qualified nonphysician health care providers.

Another important Commission initiative in health care -- one that has been questioned in the earlier hearing -- has been to challenge the suppression by professional groups of truthful, nondeceptive advertising that can help consumers choose among health care service providers. For most of the twentieth century, medical societies and licensing boards proscribed advertising by physicians. These bans came in the nineteenth century, when physicians attempted to prevent false or deceptive advertising of medical remedies -- the so-called "snake oil" cases. Unfortunately, the bans affected more than snake-oil pitches. Virtually all advertising, good and bad, fell under these edicts. By the late 1970s there was a developing consensus that professional groups' efforts to regulate advertising and other forms of competition had gone too far.

Although the Commission takes pride in its efforts to eliminate restraints on truthful advertising, the U.S. Supreme Court took the first important steps in this area with its decisions that professionals had a First Amendment right to advertise. In the Virginia Board of Pharmacy[1] and Bates[2], the court concluded that some ethical restraints on advertising injured consumers by restricting the dissemination of truthful, nondeceptive information.

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[1] Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976).

[2] Bates v. State Bar of Arizona, 433 U.S. 350 (1977).

The Commission's policy reflects this conclusion. Our efforts to prevent needless restrictions on truthful advertising certainly have enjoyed a broad consensus among policymakers; these actions had the equally enthusiastic support of Democrat Michael Pertschuk, who was chairman when the Commission handed down its decision in the American Medical Association case,[3] and Republican James Miller, who was chairman when the Commission's decision was affirmed by the Supreme Court. The Commission's work in this area has received support from such diverse groups as the Washington Business Group on Health, the United Steelworkers of America, the American Association of Retired Persons, and the American Nurses Association.

How have medical groups' efforts to prevent truthful, nondeceptive advertising harmed consumers? Some examples include physician groups that used advertising restrictions:

> -- to suppress truthful information about a low-cost cardiac stress clinic operated by a church group;[4]

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[3] American Medical Ass'n., 94 F.T.C. 701 (1979), aff'd, 638 F.2d 443 (2d Cir. 1980), aff'd mem. by an equally divided Court, 455 U.S. 676 (1982).

[4] 94 F.T.C. at 826-27 (Initial Decision).

-- to prevent an occupational health clinic from truthfully informing local employers of its programs to prevent, as well as treat, on-the-job injuries;[5]

-- to drive a physician house call service out of business;[6]

-- to prevent doctors in an area with a large elderly and Spanish-speaking population from truthfully informing consumers that they accept Medicare assignments or speak Spanish.[7]

The Commission is confident that its program of challenging restraints like these has improved consumer welfare.

In your April 4 statement, Mr. Chairman, you suggested that by acting to lift restraints on advertising by medical professionals, the Commission "gave the green light to claim-anything advertising, and short-changed patient safety." Apparently there has been some confusion about the Commission's health care cases, and I would like to rectify that now.

To the extent that the Commission gave a "green light" to anything, it was to the advertising of non-deceptive information. Of course, we would all agree that false or deceptive advertising is harmful to consumers. Thus, every Commission order in every advertising-restraint case involving state boards or professional medical associations has explicitly permitted the adoption and enforcement of rules against false or deceptive advertising.[8] From the outset of its program in this area, the Commission has recognized that professional self-regulation has an important role to play in preventing false or deceptive advertising. And medical associations understand this. Indeed, two of the specialty groups that testified at the April 4 hearing, the American Society of Plastic and Reconstructive Surgeons and the American Academy of Facial Plastic and Reconstructive Surgery, have strong ethical policies against misleading advertising by their members.

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[5] 94 F.T.C. at 821-22 (Initial Decision).

[6] 94 F.T.C. at 846-48 (Initial Decision).

[7] Broward County Medical Association, 99 F.T.C. 622 (1982).

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[8] The Commission's orders against private medical associations explicitly permit the associations to adopt and enforce reasonable guidelines to prohibit advertising that the associations reasonably believe would be false or deceptive within the meaning of the Federal Trade Commission Act. See, e.g., Michigan Association of Osteopathic Physicians & Surgeons, 102 F.T.C. 1092 (1983).

The Commission's orders against state boards have similar provisions, except that those provisions incorporate the false and deceptive standard of the particular state, rather than the standard of the Federal Trade Commission Act. For example, the Commission's order against the Louisiana State Board of Dentistry provides:

> (N)othing in this Order shall prevent the Board from adopting and enforcing reasonable rules, or taking disciplinary or other action, to prevent advertising that the Board reasonably believes to be fraudulent, false, deceptive or misleading within the meaning of Louisiana Revised Statutes §§ 37:775(3), 37:776 (12), 37:776 (16) or any Louisiana statutory provision governing dental advertising enacted subsequent to the date this Order becomes final, as limited by the First and Fourteenth Amendments to the United States Constitution.

106 F.T.C. 65, 71 (1985).

What this means is simple. The Commission's antitrust law enforcement program presents no obstacle to effective regulation of false or deceptive advertising by medical associations, state medical boards, or state attorneys general. The antitrust laws do limit the ability of medical societies and medical boards lacking "state action" immunity to police deception by imposing flat bans against advertising. The antitrust laws require self-regulators to identify which ads are truthful and which are deceptive; arbitrary rules suppressing broad categories of truthful advertising are not the appropriate weapons against deception. This requirement, that regulators distinguish between truthful and false advertising, in some respects complicates the task of regulation. But the Supreme Court has recognized that such a requirement provides benefits to consumers:

> Our recent decisions involving commercial speech have been grounded in the faith that the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.[9]

All of this may become clearer if we look at the Commission's first major case in this area, the American Medical Association case. Two important principles pertinent to these hearings emerged from this case. First, with respect to advertising by physicians, the evidence showed that consumers would benefit if the AMA's advertising ban was lifted, so that competent physicians could provide truthful, nondeceptive information about their services to consumers. In its opinion lifting the ban, the Commission found that "the AMA has a valuable and unique role to play with respect to deceptive advertising." The Commission's order expressly "permits AMA to deal effectively with all forms of deceptive advertising, including unsubstantiated representations, affirmative misrepresentations (express or implied), and representations that are deceptive for failure to disclose a material fact."[10] Thus, the Commission explicitly endorsed efforts by the AMA and its affiliated state medical societies to prevent false or deceptive advertising by their members. The Commission also noted that most physicians can be expected to advertise honestly, and for those who do not, most states have statutes prohibiting false or deceptive advertising and medical licensing boards that can take action in the event that abuses occur.[11]

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[9] Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 646 (1985).

Second, with respect to concerns raised by the AMA about the problem of incompetent practitioners, the evidence showed that the problem was the poor quality of care provided by some practitioners, not advertising, and that most of the practitioners the AMA cited as providing negligent treatment were the subject of state licensing board proceedings.[12] Moreover, the AMA's ban on advertising had little, if any, effect on the quality of care, since most incompetent practitioners were not members of any medical society, and therefore were not subject to medical society discipline.[13]

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[10] American Medical Association, 94 F.T.C. at 1029, 1030-31.

[11] *Id*. at 1009-1010.

Because of its general scope, the AMA case affected physicians in all specialties. With regard specifically to plastic surgeons, the Commission has not brought an antitrust challenge against any plastic or cosmetic surgery organization for impermissibly regulating advertising. The Commission has, however, conducted one major investigation that involved an examination of possible anticompetitive activities by plastic surgeons.

This investigation involved allegations that the American Society of Plastic and Reconstructive Surgeons (ASPRS), a group of physicians certified by the American Board of Plastic Surgery, was attempting to exclude other apparently qualified physicians from the practice of plastic surgery. Members of ASPRS allegedly challenged hospital privileges and yellow-page listings of their non-ASPRS competitors, even though those competitors claimed to be qualified to perform plastic surgery. Among those allegedly subject to exclusion attempts were physicians who were not members of ASPRS but who held certification from other boards that (1) were recognized by the American Board of Medical Specialties (ABMS), and (2) required, as a condition of certification, evidence of skill in plastic and reconstructive surgery of a portion of the body.[14]

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[12] 94 F.T.C. at 895 (Initial Decision).

[13] Id.

The Bureau of Competition recommended against a complaint against ASPRS. Essentially, the Bureau concluded that it should not proceed because it had no direct evidence linking ASPRS with its members' local activities.

The Commission accepted the Bureau's recommendation and closed the case in February 1980. The Commission is unable to tell you precisely why it accepted the Bureau's closing recommendation because the Commissioners at that time, none of whom still serve on the Commission, only recorded their votes, not their reasoning. One consequence of the decision should be obvious. A decision not to prosecute can hardly have deterred physician groups, medical boards or state attorneys general from challenging false or deceptive advertising by physicians.

Throughout this same fifteen-year period, the Commission has been active in protecting consumers from false or deceptive representations in the promotion of health care products and services. The Commission has initiated hundreds of investigations and filed scores of cases that challenged deceptive or misleading representations in this area. Many of these actions have involved marketing efforts by medical professionals, including physicians, chiropractors, dentists, hospitals and clinics. Several have involved cosmetic procedures, such as chemical face peels and hair implants. Since 1983 alone, the Commission has brought more than 40 cases that sought to bring to an end to apparently deceptive advertising of health claims. These cases include challenges to the promotion of certain diet substances as effective in reducing the risk of cancer,[15] and the marketing of products seeking to cure or prevent baldness,[16] as well as challenges to the advertising of services offering "cold laser facelifts" as an alternative to plastic surgery.[17]

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[14] At least four ABMS-recognized specialty groups have to demonstrate qualifications in plastic surgery of a particular part of the body in order to achieve certification: Ophthalmologists; Otolaryngologists; Orthopedic surgeons; and Dermatologists.

Our efforts to protect the public from the deceptive sale of health care products and services often result from liaison with a variety of public and private organizations. We frequently initiate projects and identify enforcement targets on the basis of our ongoing contacts with other federal and state officials. For example, the Commission works closely with the Food and Drug Administration and the United States Postal Service in education and enforcement efforts designed to protect consumers from health care fraud and quackery. Other initiatives result from information we obtain from private groups and professional associations. In this regard, we are working cooperatively with consumer groups, such as the American Association of Retired Persons, to identify consumer problems and to produce joint consumer publications that assist consumers in their selection of medical goods and services. The Commission's health care program has undoubtedly saved consumers millions of dollars that might otherwise have been wasted on unproven or quack products or services.

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[15] General Nutrition Corp., Inc., Docket No. 9175, Feb. 2, 1989.

[16] FTC v. California Pacific Research, Inc., et al., Civil Action No. N-88-602-BRT, U.S. Dist. Ct. of Nevada, Nov. 14, 1988.

[17] Spinal Health Services, Inc., et al., 102 F.T.C. 1319 (1983).

With regard to FTC activities relating to physicians' advertising of cosmetic surgery procedures, we note that these hearings have covered issues ranging from advertising that may be false or misleading to patients who are put at risk by the competency of particular physicians. These are both important issues, but they should not be confused with one another. False and misleading advertising for cosmetic surgery is, and should be, a matter of concern to all agencies and organizations, public and private, at both the federal and state level, that have responsibilities for regulating it. This concern is shared by the Federal Trade Commission.

Quality of care and physician competency is also, of course, a very important issue, but it is not an issue that the Commission can, or should, regulate. Issues such as the physician's competency or the ultimate safety of a medical procedure are clearly within the purview of the state medical boards. To the extent that advertising by these providers raises deception issues as well, regulators may need to proceed against that advertising. But advertising regulation is not a substitute for action to assure that practicing physicians meet standards of competence consistent with the need to protect the health and safety of the public.

We have already described some of the cases we have brought under the Commission's law against deception. As we have explained in a recent statement to this Subcommittee, the rules governing advertising provide that deception occurs when a claim is likely to mislead reasonable consumers to their detriment.[18] It is noteworthy, however, that advertising by physicians of surgical procedures often comprises only a small part of the information that a patient receives. As you know, the practice of medicine includes individual doctor/patient consultations where risks should be individually explained. When surgery is recommended, the patient is asked to provide his or her "informed consent" to the procedure that is to be undertaken. This longstanding ethical requirement is not only for the ultimate protection of the patient but also for the legal protection of the doctor. This difference is important in weighing issues about what information might be required in advertising, particularly when such information is routinely provided to patients at the doctors' offices.

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[18] See statement of the Federal Trade Commission dated March 9, 1989, before the House Committee on Small Business, Subcommittee on Regulation and Business Opportunities.

Finally, the Commission's observation to this Subcommittee concerning the promotion of infertility services by physicians is also true about the marketing of cosmetic surgery. Such procedures are generally practiced and promoted at a local level and, therefore, consumer protection must, at least initially, be the prime responsibility of the state medical boards and the state consumer protection authorities. FTC intervention in essentially local advertising and promotion by individual physicians should, therefore, be cautious and selective.

With this context, I would like to describe for the Subcommittee the Commission staff's ongoing efforts with regard to advertising of cosmetic surgery procedures.

First, staff has been working closely with representatives of the American Society of Plastic and Reconstructive Surgeons on certain concerns that group has about advertising in this area, and we are providing ASPRS with advice and assistance as we discuss with them how best to measure consumer understanding of certain claims frequently used in physicians' advertising.

Second, staff is in contact with other professional medical groups, such as the American Board of Medical Specialties, the American Board of Otolaryngology and the American Board of Cosmetic Surgery, as well as various experts in the field to develop information on such issues as the extent to which other medical specialties are trained in plastic surgery procedures and what criteria the boards apply for certification.

Third, staff is in contact with the Federation of State Medical Boards, as well as individual state medical boards across the country, in order to assess the extent to which they believe the advertising of cosmetic surgery procedures or the competence of physicians to provide such procedures to be a problem; what measures, if any, they have taken to address that problem; and how we can help in that effort. Several medical boards have told staff that consumers do not ordinarily complain to them about cosmetic surgeons' advertising; typically, the complaints they receive about advertising come from competing doctors or their professional associations. Moreover, the individual medical boards have indicated to staff that they have not seen many instances of incompetence in the performance of cosmetic surgery procedures; where there are incidents of such problems, the Boards are proceeding with individual disciplinary measures.

Fourth, our regional offices are helping headquarters staff gather and examine examples of local advertising from around the country so that we can better understand how the services are generally marketed and identify any potentially deceptive claims.

Fifth, staff is in contact with several advertisers of cosmetic surgery procedures, seeking information on claims they have made about their procedures. Based on the information provided to staff in response to these contacts, appropriate action will follow.

Sixth, staff is preparing consumer education pamphlets, which will provide consumers with basic information on how to select a plastic or cosmetic surgeon. These materials will likely address issues such as what information to ask about when considering cosmetic or plastic surgery, ways to assess a doctor's competence and experience, and what to ask about the safety of the procedure, its risks and its side effects.

Based on what the staff has seen so far in our ongoing review of advertising in this area, it appears that certain issues bear further scrutiny, among which are:

> -- Representations regarding the safety of a particular cosmetic service or procedure. In general, the

Commission will require that the advertiser possess a relatively high level of substantiation for claims that raise issues of consumer safety.

-- The use of before and after pictures to demonstrate the results one can achieve by using the product or service. In reviewing this type of claim, the Commission will consider whether the pictures are accurate and unaltered depictions of the results obtained by the subject portrayed.

-- The use of board-certification claims. Our staff is examining whether a claim of board certification that does not specify the area of specialization needs further clarification.

Since this last issue received extensive attention at the hearings in April, some additional comments may be helpful. A representation concerning certification of a specialty would seem to be material to a consumer's choice of physicians. A physician's claim of board certification may be understood by the public as implying that the physician has advanced training or experience in the field of certification and that the physician's competence has been evaluated by a knowledgeable body.

If an advertisement claims board certification, and the certification has no relevance to the area of practice advertised, that representation should prompt serious concern. On the other hand, where the advertised certification is from a board that requires demonstrated skill in the area of practice advertised, then it appears unlikely that consumers could be deceived. For example, since otolaryngologists must demonstrate proficiency in plastic and reconstructive surgery of the head and neck to become certified by the American Board of Otolaryngology, deception would seem unlikely to result if a board-certified otolaryngologist advertised board certification in connection with an offer to perform plastic surgery of the head and neck.

We are also aware of criticisms that have been voiced at these hearings concerning claims in advertising by cosmetic surgeons of board certification by medical specialty boards that are not affiliated with the American Board of Medical Specialties. Undoubtedly, ABMS' private voluntary confederation helps maintain high standards for various medical specialties within its ambit. Yet many of the alternative certification bodies may also serve a useful function for the public. For example, information about a physician's advanced training or special skills can be particularly useful to consumers in selecting a physician, and legitimate board certification from either ABMS or non-ABMS boards can be an important indicator of advanced training and skill. In addition, the opportunity to publicize certification may give physicians an incentive to obtain advanced training or special skills. Because differing certification programs can provide different information that may be of value to consumers, they should not be discouraged so long as they are what they purport to be. Thus, physicians' dissemination of truthful, nondeceptive information about board certification by legitimate certifying bodies should not be inhibited. It should be emphasized, however, that when certification is not bona fide, a claim of certification in a particular area raises serious legal concerns.

As noted earlier, almost all of the advertising by cosmetic surgeons takes place at the local level, and the local medical boards have the jurisdiction and responsibility, as well as the expertise, to act against doctors who promote their services deceptively or who perform these procedures incompetently.[19] The authors of the recent ABA Report on the role of the Federal Trade Commission emphasized the need for the states to assume responsibility for cases that are primarily intrastate in nature, and for the Commission to deal with advertisers who affect the national economy.[20] As the ABA report notes, "where the FTC is challenging what is essentially a local practice, the enforcement process may be unduly expensive and insufficiently responsive to local concerns." Moreover, the report cautions that "advertising practices should be addressed by the preferable enforcer. When the FTC learns of a questionable advertisement with a principally local effect, the FTC should refer the matter to the appropriate state and offer to help."[21]

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[19] In this respect, I should also add that the private medical societies usually have standards in effect that address deceptive advertising, and they can, and should, police their own membership to prevent deception. As the Commission emphasized in the AMA case, such organizations have a valuable and unique role to play with respect to deceptive advertising and oppressive forms of solicitation by physicians.

In emphasizing the role of the state boards, the Commission does not intend to deny the role that it can play. Should the Commission's ongoing review of advertising identify claims for surgery procedures that are false and misleading, it can, and does, choose to proceed directly against such advertising where it has interstate effects. The Commission can, and does, encourage state medical boards and attorneys general to follow up with actions of their own against local practitioners who may be engaged in similar activities within their jurisdiction. The Commission has used such an approach in fertility clinics, and in another area of advertising of cosmetic procedures, namely in the field of cold laser face lifts.[22] In both areas we brought cases against providers of these services under Section 5 of the FTC Act, challenging their claims as false and deceptive. In preparing the cases, the Commission staff developed expert testimony on the efficacy of the procedure and a theory for proving that the claims that the defendants had made for the process were false and misleading. The Commission staff has made available its evidence and expertise to assist state boards and attorneys general who might want to initiate their own actions. Finally, in an effort to aid consumers in evaluating the efficacy of laser face lifts, the Commission published consumer education materials.

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[20] Report of the American Bar Association Section of Antitrust Law, Special Committee to Study the Role of the Federal Trade Commission, April 7, 1989.

[21] _Id._ at 39-40.

[22] Cold laser face lifts are not to be confused with the techniques employed in laser surgery. The instrument employed (continued...)

The staff of the Subcommittee has advised us that some state medical boards, nonetheless, may feel inhibited in acting to bar deceptive advertising by local practitioners because of the FTC's interest in promoting healthy competition among physicians. We hope this statement today has made clear that there is no conflict between healthy competition and effective regulation of deception. As you know, the Commission strongly believes that stifling the flow of accurate and truthful information in advertising is anticompetitive and not in the best interests of consumers. By the same token, prohibiting false, misleading and deceptive advertising promotes the interests of consumers. The

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[22] (...continued) in the former procedure produced a cold laser beam similar to those used in uniform product code scanners in retail stores and was deceptively advertised as accomplishing lasting results similar to surgical face lifts.

Commission welcomes the opportunity these hearings present to clear up any confusion that may exist concerning the importance of both competition and consumer protection in serving consumers of medical services.

In summary, the Commission will continue to monitor and, where appropriate, act to challenge actions by state medical boards that prevent physicians from advertising truthfully and nondeceptively. We will also work with those boards to identify and eliminate deceptive advertising by physicians, and, where appropriate, bring our own actions to prohibit it. Finally, we will continue to work with your staff and others who are concerned about deceptive advertising.

These hearings have demonstrated the potentially devastating effects of choosing the wrong surgeon for cosmetic surgery. They have also demonstrated that there is no simple solution to addressing the various factors that can lead to the sometimes tragic consequences of such a choice. Eliminating deceptive claims in advertising is an important endeavor in which the Commission, state medical boards, state attorneys general and private medical societies, all can play an important role. The more important issues of weeding out incompetent surgeons and assuring patient safety, however, must be addressed by the state licensing boards and the medical profession itself.

Thank you for the opportunity to appear here today and present this summary of the Commission's activities. I shall be happy to answer any questions that the members of the Subcommittee may have.

OFFICE OF
THE COMMISSIONER

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

May 30, 1989

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation and Business Opportunities
Committee on Small Business
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Wyden:

The testimony to be delivered by Chairman Oliver was circulated for approval by the Commission, but failed to obtain the support of a majority. This letter is to set forth my separate views. Although I agree that the Commission properly can take pride in its efforts and accomplishments both to eliminate deceptive advertising and to eliminate harmful restraints on truthful advertising, I am concerned that overly zealous extensions in some of these endeavors actually may inhibit or restrict legitimate efforts by the states to protect consumers.

I question the assertion at page 6 of the testimony that the Commission's antitrust enforcement program poses no obstacle to regulation of false or misleading advertising. Recent enforcement actions raise the question whether the Commission is going too far in challenging efforts by the states to regulate false or misleading advertising. In early cases, such as *American Medical Association*, 94 F.T.C. 701 (1979), *aff'd*, 638 F.2d 443 (2d Cir. 1980), *aff'd mem. by an equally divided Court*, 455 U.S. 676 (1982), the Commission challenged total bans on advertising and solicitation and concluded, I believe correctly, that such sweeping bans are anticompetitive.

Those cases, which seem easy in hindsight, have given way to Commission attacks on particularized state board regulation of advertising, including regulation to preclude deception. In *Texas Board of Chiropractic Examiners*, 54 Fed. Reg. 13695 (April 5, 1989), the Commission majority tentatively accepted for comment a consent order that requires the Texas Board, within thirty days, to eliminate or revise fifteen board regulations. Although some of those regulations potentially have anticompetitive effects, others merely implement state statutory prohibitions against fraud and deception. I filed a brief dissent in that case, which is enclosed for your convenience.

My dissent stemmed from a concern that the Consent Order against the Texas Chiropractic Board may undercut the ability of that state agency to stop fraud and deception. The Order prohibits the board from adopting or enforcing any rule "that prohibits or seeks to prohibit chiropractors from advertising or solicitation." Although the Order has a proviso that allows the board to adopt and enforce rules to prevent advertising that the "Board reasonably believes to be false, misleading or deceptive within the meaning of Section 17b of the Chiropractic Act of Texas...," the proviso actually gives the board little leeway to put an end to deceptive practices because it limits the Board to prevention of deception under only one Texas statute. The proviso does not allow the Board to adopt or enforce rules on advertising under the existing provisions of Section 14a (2), (5), (6), (8), and (16) of the Texas Chiropractic Act, Vernons's Ann. Civ. St. art. 4512b, Section 14a, and does not allow the Board to enforce Texas statutes (other than Section 17b) on fraud and deception that may be enacted in the future. Moreover, since the Commission majority is requiring the Texas board to eliminate regulations that it adopted to constrain deceptive practices, I doubt that the board members will feel at liberty to try to fashion new approaches to combat deception.

In the years since the AMA decision, many extreme restraints on professional advertising have been eliminated. At this point, the Commission needs to assess how much further to press enforcement actions that might chill state board efforts to protect consumers. Everyone agrees that states have the authority to stop fraud and deception. The question is how much latitude is available to state boards to adopt regulatory approaches to prevent questionable advertising practices that differ from the regulatory approach of the Federal Trade Commission under Section 5 of the FTC Act. I believe that the antitrust state action doctrine accords state boards considerable leeway to implement state statutory policies against fraud and deception.

In addition, I have reservations about the suggestion that in a case under Section 5 of the Federal Trade Commission Act, state regulatory agencies have the burden of proof to demonstrate that they adopted the least restrictive possible regulatory approach to preventing fraud and deception. Quite apart from the formal state action doctrine, principles of federalism cause me to question whether the Federal Trade Commission should establish itself as a supra-legislature pronouncing for each state board which, if any, of its regulations is optimal.

I also find the discussion at pages 12-13 of the Commission testimony inadequate to explain what I consider to be the agency's proper role with respect to the issues of quality of care and physician competency. Most assuredly these are important issues that are not appropriate subjects for FTC regulation. As other congressional committees have emphasized over the years, assessment of the quality of care provided by a physician or other health care professional requires expertise that the Commission does not possess and that falls outside the scope of the agency's mandate to protect consumers from unfair and deceptive marketing practices. The FTC is competent to evaluate the functioning of the market in commercial terms. It cannot, however, judge the professional competence of those trained to deliver health care services. The regulation of these professionals properly rests in the peer review systems and with the professional societies and state boards that possess the necessary expertise to make informed decisions about quality of care.

When marketing abuses, which are within the Commission's expertise, arise in the health care area, the Commission must move and, I believe, has moved vigorously to challenge them. Professional societies and, to some extent, state boards, notwithstanding their appropriate and important role in regulating the actual provision of health care services, may engage in conduct that is unlawful under federal antitrust or consumer protection statutes. In proceeding against this misconduct, however, the Commission must take care to avoid imposing undue restrictions that will preclude these organizations from carrying out legitimate efforts to regulate the performance of health care professionals.

The discussion at pages 16 to 18 of the testimony warrants comment. You should be aware that the views in this section of the testimony reflect a position that the Commission has declined to permit its staff to present in a proposed advocacy filing. Recently, the Oklahoma State Board of Medical Licensure and Supervision proposed rules to regulate advertised claims of board certification in order to correct what it perceived as an abuse by so-called "certification mills." The FTC staff proposed to intervene, not to support the effort to halt the abusive use of bogus certifications, but rather to urge the Oklahoma Board to weaken its proposed rule. The staff sought Commission authorization to file an advocacy comment opposing the proposed rule, but failed to win majority support at the Commission to authorize the filing. Not only do the views at pages 16 to 18 not reflect a position that the Commission has adopted, but also this position was advanced to the Commission and failed to win support.

Regulation of advertising claims of medical board certification poses difficult questions for the Commission. In considering the extent to which consumers may be either assisted by or confused and misled by certain claims, and whether there is reliable evidence to conclude that particular state board regulations restrain competition, the Commission must always be vigilant in recognizing the limits of its own expertise. Although the questions are not easy, the Commission should address them fully before presumptively condemning advertising regulation by others.

The Commission's enforcement actions on advertising restraints have been successful in eliminating many anticompetitive state and association advertising regulations. A real concern, however, exists about pushing too far and chilling legitimate state efforts to prevent consumer deception.

Sincerely yours,

Mary Azcuenaga

Mary L. Azcuenaga

Enclosure

DISSENT OF COMMISSIONER MARY L. AZCUENAGA

Texas Board of Chiropractic Examiners

File No. 871-0025

I dissent from the decision to accept this consent order for public comment. The Order requires the Texas Board of Chiropractic Examiners to delete or revise fifteen rules. Some of those rules relate to matters of public health and safety or to the prevention of consumer fraud or deception. These are matters that the Texas legislature authorized the Board to regulate and appear to be protected from antitrust challenge under the state action doctrine. In deciding whether finally to accept this consent order, I would welcome public comment on the scope of the Board's statutory authority and whether the Order threatens to impair the Board's ability to implement state policy. Comment also would be useful on the propriety of the balance that has been struck between protecting competition and protecting consumers against fraud, deception and potential health and safety risks. In particular, I would welcome comment on rules 75.1(5), 75.1(6), 77.2(2), 77.2(8), 77.2(9), 77.2(10), 77.4(b), and 77.5(b).

OFFICE OF
THE COMMISSIONER

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

May 30, 1989

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation, Business
  Opportunities and Energy
Committee on Small Business
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Wyden:

Thank you for your letter requesting testimony concerning the history and role of the Federal Trade Commission ("FTC" or "Commission") in regulating the advertising and marketing of cosmetic surgery procedures. I have taken the liberty of sending this response to outline my views on the proper role of the FTC in this important area.

At the outset, I share the Subcommittee's interest in issues regarding patient health and safety. In this regard, I am firmly convinced that many regulations involving professionals, and health and safety regulations in particular, are necessary to protect consumers from incompetent or unscrupulous providers of medical care. Thus, regulations carefully designed to ensure that professionals possess necessary skills (such as educational and training requirements) are desirable from the consumer's point of view. Similarly, high professional standards are fostered by laws and regulations governing physician conduct (such as standards against dereliction in performance and certain advertising and solicitation statutes).[1]

Responsibility for enforcing these standards is shared by the states, professional self-regulatory organizations and the FTC. Some areas, such as those that require judgments about the quality of medical care, appropriately are left to those agencies or organizations possessing the expertise to make such judgments. The Commission does not have such expertise and, therefore, should not intrude in these areas.

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[1] *See American Medical Association*, 94 F.T.C. 701, 952-53 (1979) (Initial Decision), *aff'd as modified*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982).

The Commission, however, does have an important role to play in the area of professional advertising. Indeed, for more than a decade the Commission has devoted a significant portion of its resources to the area of professional advertising. For the most part, the Commission's past activities have been in the public interest.

The Commission's role in the area of professional advertising is two-fold. First, the Commission has a responsibility to protect consumers from unfair or deceptive advertising. Such advertising is inefficient from an economic perspective, and hurts honest professionals. Of even more importance, vigorous action to thwart unfair or deceptive advertising is needed to guarantee that consumers receive medical care that is safe and of the highest quality.

Second, the Commission has an obligation to ensure that consumers have access to truthful, fair, and non-deceptive information about prices and services. Thus, the Commission appropriately should challenge under the antitrust laws or under its unfairness jurisdiction unfair or unreasonable restrictions on truthful and non-deceptive advertising imposed by state or private organizations.

Of course, the Commission's authority to challenge state or private restrictions on professional advertising is limited. First, the "state action" doctrine prevents the Commission from challenging under the antitrust laws state statutes or rules where there is a clearly articulated and affirmatively expressed state policy to displace competition and where the state actively supervises the regulatory plan. Second, basic notions of federalism permit state and federal regulatory schemes to mutually coexist. Simply because a state regulatory plan is different from or even broader than the Commission's is not in itself a basis for FTC challenge. Third, in any FTC challenge to either a state or private restriction on professional advertising, the Commission bears the burden of proving that the challenged restriction is an unfair method of competition or an unfair act or practice. This means that the Commission must consider not only the costs imposed by the restriction, but also the benefits gained by consumers as a result of the regulation.

In short, the Commission should not impinge upon the states' valid interests in ensuring that consumers receive high quality services from professionals. Thus, the Commission ought to avoid gratuitously diminishing the effectiveness of the states in securing adequate service quality by professionals. Similarly, requirements by professional associations that are reasonably related to health and safety concerns are likely to be legitimate regulations that enhance rather than harm consumer welfare.

In sum, the obligation to permit professional advertising bears with it the responsibility to ensure that the ensuing advertising is not unfair or deceptive. As a commissioner, I take both duties very seriously. The Commission should aggressively police against unfair or deceptive advertising. At the same time, the Commission should not shy away from challenging advertising restrictions where there is reason to believe those restrictions would violate Section 5 of the FTC Act.

Thank you for the opportunity to comment on this timely topic. If I may be of any further assistance, please do not hesitate to contact me.

Sincerely yours,

Andy Strenio

Andrew J. Strenio, Jr.
Commissioner

Chairman **Wyden**. Thank you, Mr. Oliver.

Your written statement indicates that the views in the statement do not necessarily reflect the views of the Commission or any other commissioner.

It is correct that your views were rejected by a majority of the commissioners; isn't that correct?

Mr. **Oliver**. That is not correct.

Chairman **Wyden**. Well, I have a letter from Commissioner Azcuenaga, if I am pronouncing that right, dated May 30. It says, "testimony to be delivered by Chairman Oliver was circulated for approval by the Commission but failed to obtain the support of a majority."

Mr. **Oliver**. Mr. Chairman, it is not customary for members of the Commission to discuss votes in public, and I am reluctant to go into the details any further than I have.

I guess my plea is that you could discuss that with Commissioner Azcuenaga, but it is not customary to answer those kinds of questions in public.

Chairman **Wyden**. This is not a national security matter. This is something that I think is in the public interest.

Do you say that the Commissioner is incorrect in making that assertion?

Mr. **Oliver**. Yes, sir.

Chairman **Wyden**. What was the vote?

Mr. **Oliver**. I prefer not to discuss the methods and procedures by which the Commission does its business in public. That is a longstanding tradition of the Commission. We don't deal in national security matters, and we never do, but even so, we don't discuss our investigations or things like that in public.

I am surprised that Commissioner Azcuenaga wrote that.

Chairman **Wyden**. Commissioner Azcuenaga and Commissioner Strenio raised serious concerns about "chilling legitimate State efforts to prevent consumer deception." Yet you told us the antitrust program presents no obstacle to effective State regulation of false and deceptive advertising.

Are you saying that these other commissioners are confused, like the States, about the FTC's message on false and deceptive advertising?

Mr. **Oliver**. No; we have disagreements, obviously, as to what the policy is, and what the effect of certain policies are.

Chairman **Wyden**. Mr. Oliver, both commissioners emphasized the importance for consumers of health competition. In fact, they essentially have the same view that I do. We strongly feel that competition has a role to play and responsible advertising is extremely important, but they also emphasize the crucial need to "protect consumers from unfair or deceptive advertising."

Isn't that the real reason that there are differences of an opinion on the Commission with respect to your statement?

Mr. **Oliver**. I think that all the commissioners agree that consumers should be protected from false, misleading, and deceptive advertising. I don't think there is any real disagreement on that point.

Chairman **Wyden**. I think it is clear, certainly in the two letters that we have received. Specifically, the two commissioners, at least, assert that you haven't struck the proper balance against fraud, deception, and potential health and safety risks with the need for helpful competition in the marketplace; isn't that correct?

Mr. **Oliver**. They certainly see it differently from the way other commissioners did; that is correct.

Chairman **Wyden**. Commissioner Azcuenaga's letter to the subcommittee points out that the FTC took issue with the Texas Medical Board's effort to stop fraud and deception in the chiropractic field. The FTC "undercut the ability of that State agency to stop fraud and deception."

The Commissioner wrote that the board would again not feel at liberty to try to fashion new approaches to combat deception, and that is what we heard from Kansas and Oregon.

Once again, you seem to be the only one who is telling us that the States don't face any obstacles to preventing false and deceptive advertising.

Mr. **Oliver**. Let me say two things about that case. That consent order is, of course, out for public comment, and the reason it is out for public comment is so that the commissioners eventually can consider any comments that come in relating to any of the issues that are covered by the order.

The Texas attorney general was advising the people who signed that order, and apparently it was his view that signing that consent order would not interfere with the ability to protect consumers.

I don't doubt that you will find people who disagree with the result. But the fact is, we think, and a lot of others apparently also think, that the consumers will not be disadvantaged as a result of that order.

I should hasten to add that we will read the comments that come in and make up our mind finally on the basis of whatever comments do come in.

Chairman **Wyden**. Why do you think the States are so frightened? We have talked to State after State. We have just heard from two at length, talking about their fear, talking about the chilling effect that they see the Federal Trade Commission having on their work.

Are these just frightened, paranoid people, or why are they saying that?

Mr. **Oliver**. I don't know the answer to that, Mr. Chairman.

Chairman **Wyden**. For his part, Commissioner Strenio cautions that the Commission "should not impinge upon the State's valid interests in ensuring that consumers receive high quality services from professionals," again I quote, "gratuitously diminishing the effectiveness of the States' ability to curb false and deceptive advertising."

If the FTC restricts legitimate regulations that enhance rather than harm consumer welfare, the Commission will have encouraged the deterioration of quality medical services.

Is there anything about that analysis of Commissioner Strenio's letter that you disagree with?

Mr. **Oliver**. If that was what the Commission had done, he would be correct; but that is not what the Commission did. We did not restrict the States' ability to promote consumer welfare.

Chairman WYDEN. Commissioner Azcuenaga emphasizes the importance of professional societies and peer review in determining professional competencies while acknowledging the potential for antitrust activities, and the Commissioner highlights their proper role in judging professional competencies.

Commissioner Azcuenaga points out the Commission must take care to avoid imposing undue restrictions that will preclude these organizations from carrying out legitimate efforts to regulate the performance of health care professionals.

Mr. Oliver, at our April hearing, we heard that health care professionals are afraid to police their own. The dissenting Commissioners' letters echoed the same concern. What message have you sent as the head of the FTC that the States and the professions don't have to worry about strong self-policing of false and deceptive advertising?

Mr. OLIVER. As I said in my statement, both the long one submitted for the record and the one that I read today, every order the Commission has issued in this makes it perfectly explicit that those organizations can indeed prevent false and deceptive advertising, and the record, I think, is very plain.

Chairman WYDEN. Would you say that you have given some definition to the States about false and deceptive advertising? Because that is one of the things that they are concerned about, that there is an absence of standards. They see these court decisions come down. The State of Kansas says the only time they have even heard from the Commission is when the FTC thinks one of their policies is being challenged.

What have you done to tell the States how to proceed in this area?

Mr. OLIVER. I suspect that in the orders that the Commission has put out which deal with the facts, particular cases with particular facts, there is the guidance that the States need to police false and deceptive advertising.

Chairman WYDEN. You may suspect that kind of information is contained in these orders, but State after State—and we have just had two from different parts of the country—have told us they don't know how to proceed in the area of false and deceptive advertising.

Mr. OLIVER. I didn't get that impression. I didn't hear all the testimony, so I can't comment on any particular examples where they thought that the FTC would step in and disapprove of what they were doing.

There was in one case a local ad in a phone book which mentions 16,000 cases and no mistakes; and I don't see any reason why, if that is false and deceptive, why the State cannot do something about it.

Chairman WYDEN. I think they are fearful. The fact of the matter is that when you have State agencies with limited resources going up against the Federal Government which in their view has sent all these messages to them that they shouldn't proceed, they are going to be understandably reluctant to do it.

My view is if the Federal Trade Commission is serious about helping the States, they would reach out and say here are some specifics, some guidelines as to how to proceed. But for one reason or another, that hasn't been done.

Possibly, there are initiatives that the Commission is planning that are going to change it, and I note with some pleasure that you say you are going to study some of these things in cosmetic surgery now, a year after we began digging out these abuses.

But I think that the States need, at the very least, some specific guidelines, if not standards, on how to proceed.

Mr. OLIVER. What I think might also be useful, Mr. Chairman, would be specific examples of advertising that you perhaps think are false and deceptive that bear investigation that we could look at, and perhaps at that point, we could tell the States whether we see a problem.

I am not aware of any issue or any kind of advertising that the States are not able to move against.

Chairman WYDEN. Are you concerned about acting on these matters generically? I mean, if a pattern is presented from the States—we just saw one example of interstate corporate activity involving, among other things, before and after ads—if those from the State of Kansas and our own advertisements that we have collected are sent to you, are you prepared to act on that and take formal action?

Mr. OLIVER. I say look to see if it is interstate activity. The point, it seems to me, is whether the activity is a local activity taking place under the supervisory authority, if you will, of the local agency. In the cases that were studied here, they were all local activities that the local boards or attorneys general can deal with.

Under those circumstances, it seems less appropriate to have the Federal Trade Commission make it a Federal case. Those are local cases, and local agencies, it seems to me, should deal with them. They have as many resources as the Federal Government has.

Chairman WYDEN. But these franchise operations are being marketed nationally. They are in local towns with local doctors under the jurisdiction of a local attorney general and a local medical board. What kind of case do you feel the FTC should get involved in?

In the views of two of the Commissioners who have written, a majority feel that antitrust impediments and other impediments have been put up against the States. Now you are telling us they cannot deal with interstate activity because it is not interstate activity, it is local.

What do you envision the Federal Trade Commission doing in this area?

Mr. OLIVER. The question is not whether we could, but should we deal with it, with cases that are interstate rather than cases that may have some interstate nexus that are essentially local cases. If patients flock from around the Nation to go to the doctors in Kansas, then you might have a different situation.

Chairman WYDEN. That is your criteria? You just gave an example.

Mr. OLIVER. It is different from where you have a local patient going to a local doctor.

Chairman WYDEN. I gather now that your standard, the standard you wish to promulgate for Federal Trade Commission involvement, is that people ought to get in their car. If they drive all over the United States and show up in Kansas, that would constitute national activity. I think that is an absurd rewriting of the Federal Trade Commission's role in protecting consumers.

I am just amazed that you have given that as an example of what would constitute the kind of national involvement that would mobilize the Federal Government. We are talking particularly in health care, where we have seen a dramatic change, a shift toward outpatient approaches and franchising. We are talking about major corporate activities that are being marketed nationally.

You have told us the standard will be if everybody goes out and drives around the country and shows up in one place, only then is it your concern. I just think that is absurd. Let me ask you about three of the areas in your testimony that you talked about.

You mentioned one, the before-and-after ads. But do you think that there now is a pattern of abuse with respect to certification, where practitioners hold themselves out in a significant number of cases to have expertise that they really don't have?

Mr. OLIVER. I don't think that we have enough information to make that assertion.

Chairman WYDEN. Are you studying that, too?

Mr. OLIVER. Yes.

Chairman WYDEN. What about making far-fetched claims without substantiation? Is that a serious problem or one that you need to study, too?

Mr. OLIVER. We don't know. Those are obviously fact cases and have to be studied on an individual basis, and I don't believe that we have enough information at this point to know about those. But again, those are claims, problems that are being dealt with at the local level.

Chairman WYDEN. Now, you discuss in your statement some issues with respect to the American Medical Association's approval of certification boards. Your view is that the ABMS approval of certification boards is not a valid method of assessing the qualifications of a physician.

The Commissioner's letter points out that the agency has specifically refused to support such a view, acknowledging de facto the danger to consumers with certification mills.

The Commission doesn't seem to share your view that an ABMS or non-ABMS board can be an important indicator of trade skill. Isn't this a problem, the weekend warriors that Dr. Johnston and Mr. Gannon were concerned about?

Mr. OLIVER. The question of certification involves competence on one level. Merely because a doctor lacks certification from a particular medical board does not necessarily mean that he is not competent to perform a particular procedure. His specialty may be narrower than any particular board will be certifying to.

So, in a case of any particular physician, it depends upon what he is claiming and what kind of service he is providing.

Chairman WYDEN. So, in your view, this weekend warrior issue of just going out and taking a 48-hour course either isn't a problem, or, if it is, it is not your problem? Is that correct?

Mr. OLIVER. No; I don't think I said that.

Chairman **Wyden**. Well, tell me again what you said on that point.

Mr. **MacLeod**. I think that you are depicting two extremes of the spectrum here. The interesting cases are the ones in between. Fraudulent diploma mills or certification mills are the kinds of cases in which we are interested.

Chairman **Wyden**. Do you believe that there is a problem with people, with physicians who have medical degrees and have State licenses going out and getting these weekend courses, and then holding themselves out as experts in an area of cosmetic surgery? Is that a problem?

Mr. **MacLeod**. I believe the chairman's testimony indicated that is precisely one of the problems we are looking into, Mr. Chairman.

Chairman **Wyden**. What I sense, and that is why I ask, is that this is something that you say is going to be studied. But that doesn't tell me a great deal.

Mr. **MacLeod**. But there is a difference between study and investigation. When we say we are investigating something, it doesn't mean that we are repairing to the library to examine hypothetical questions. We are looking into it.

Chairman **Wyden**. We have had virtually every medical group come before us and say that the people who take the 48-hour courses represent a serious problem. I don't understand how anybody with a reasonable orientation toward health care, who favors competition and advertising, would say otherwise.

But for some reason, you don't seem to say it is a problem.

Mr. **MacLeod**. No; that is not at all what we said.

Chairman **Wyden**. Tell me what you say and what you are going to do about it.

Mr. **MacLeod**. What I have done and what we are doing right now with some of the certifing boards is working together to determine precisely the meaning and precisely the qualifications that are involved with the various boards.

There are some boards that are not ABMS boards that have even appeared before you and have represented to you that they deserve every bit as much recognition as some ABMS boards.

That is not necessarily a determination for the Federal Trade Commission to make, but there are boards that run the spectrum from the very top of the line to some of the ones that represent certification mills.

For the Federal Trade Commission, the issue of investigating and bringing a section 5 enforcement action happens to be whether or not the board is representing itself to be something other than what it is, or a physician is advertising something more than that physician is actually qualified to do.

That is precisely what we are investigating, and if and when we can find some cases that show that we can make that presentation, that we can make that proof, then that is precisely the kind of case that we will be coming forward with.

Chairman **Wyden**. But medical groups have been talking about this problem of somebody taking a 48-hour course for a long, long time, and you are saying if we can find some cases——

Mr. **Oliver**. Mr. Chairman, are you suggesting that those people are not qualified?

Chairman WYDEN. No; what I am saying is the idea of holding yourself out as an expert on the basis of a 48-hour course, based on what medical practitioners have told this subcommittee in sworn testimony, is misrepresentative, and for some reason, the Federal Trade Commission thinks that we ought to doddle, and study, and analyze, and do various other things, when virtually everyone else we have talked to and everyone else who has come before this subcommittee says that this is a substantial and immediate problem.

Mr. OLIVER. Are you suggesting that those people are not competent after the weekend courses?

Chairman WYDEN. I am suggesting that the sworn testimony we have heard from medical practitioners is that it is misrepresentation to hold oneself out as an expert after 48-hour course. That is what I am saying.

Mr. MACLEOD. Mr. Chairman, a year ago, I went before some board-specialized physicians and said, bring me your ads. We have been working with your staff, and I have been asking your staff, bring me your ads. You bring me the ads, and I will bring the investigations.

I cannot investigate testimony from this subcommittee.

Chairman WYDEN. I will be happy to do it. I have a very good staff. Mr. Papineau is excellent, as are Ms. Murphy and Mr. Jenning. But they will not be able to do all the work for the Federal Trade Commission on fertility uses and some of the other areas that we have been digging into.

We will provide you with the ads, but I am not aware that the Federal statutes and the statutory obligation of the Federal Trade Commission consists of our small staff bringing you cases of abuse. I think the gentleman from California would like to ask some questions. I think we could do 5 minutes of questions, and I have certainly had more than that for an opening round.

Why don't we let the gentleman from California get 5 minutes in, and then we will take a break and come back.

Mr. CAMPBELL. I would be pleased to break now if you intend to come back.

Chairman WYDEN. Yes.

Mr. CAMPBELL. Should we go vote?

Mr. OLIVER. Mr. Chairman, I have a Commission meeting at 3:30.

Mr. CAMPBELL. In that case, I will be happy to proceed with my 5 minutes. Thank you, Mr. Chairman. I regret the timing problem, so let me be brief.

The first point is that for the record and for you, Mr. Chairman, the practice of individual letters from Commissioners, in my experience, is sometimes misleading. It would be helpful in my judgment if the individual Commissioners would be asked to testify so that perhaps we could have Commissioner Azcuenaga and Commissioner Strenio here to express points.

Chairman WYDEN. We are going to ask Commissioner Azcuenaga to do it, because I find it most curious that Commissioner Azcuenaga has stated in writing that the chairman's views have been rejected by a majority of the Commission, and the chairman states otherwise.

So, this is a most curious matter, in my view, and it is something we will want to follow up.

Mr. **Campbell**. I do note for the record that Commissioner Azcuenaga's testimony says, "failed to obtain a support of the majority," which perhaps might be the phrasing that would include you as to what is going on. But there is no substitute for live people talking to you.

In my short experience at the Federal Trade Commission, it was standard practice for Commissioners of different persuasions on an issue to send up points of view.

Chairman **Wyden**. If the gentleman would yield. These two Commissioners specifically requested that their points of view be included in the record.

Mr. **Campbell**. I am pleased that they will be, and I am pleased that they will appear here, so I can put live questions to them.

I will put this in the form of a question, given the shortness of time, Mr. Chairman. Chairman Oliver, is it not true that in regard to whether the FTC has given advice to States on peer review, that in 1982, the FTC issued a Commission opinion saying that peer review of fees was permissible, and in 1986, in Eyeglasses II, dealt with advertising peer review, and in each case authorized explicitly State peer review and peer review by professionals?

Mr. **Oliver**. That is correct.

Mr. **Campbell**. Mr. Chairman, with your permission, I would like to make part of the record, Eyeglasses II, which is the most recent statement by the Federal Trade Commission on medical practices.

Chairman **Wyden**. Without objection.

[The information is in subcommittee files.]

Mr. **Campbell**. In that, you would find reference to peer review and the explicit statement that States may proceed in that fashion. Chairman Oliver, your view of Federal nexus I did not take to be whether a victim drove from State to State.

I rather took it to be whether there was a code for Federal intervention in the adequacy of Federal, State, and local supervision. Could you elaborate?

Mr. **Oliver**. That is correct. I think in the local case, given the way I understand these rules, that we would probably have the jurisdiction. That is not the point. The point is whether we should make it a Federal case that the Federal Trade Commission extends its resources on, or whether a local medical board or local attorney general can handle that situation.

In our judgment, a local matter like that should be handled by a local enforcement office.

Mr. **Campbell**. May I ask the staff comparison between those investigators and professionals in State enforcement agencies and the Federal Trade Commission? Do you have for me a ball park figure as to how many officials there are in State and local agencies investigating deceptive and fraudulent advertising versus how many at the Federal Trade Commission?

Mr. **Oliver**. I heard one gentleman say this afternoon that there were 28 in the Kansas Attorney General's office and 20 attorneys in the Kansas Medical Board or Board of Healing Arts. That is a total of 48. We have something like 350 attorneys who do this kind of work. But if there are 48 in Kansas, there are probably similar numbers in the rest of the States, and it would look to me that they have more resources.

Mr. CAMPBELL. If the FTC were to assign its 350 attorneys to each of the 50 States, I take it you would agree that there would be seven assigned to Kansas if we were to assume that Kansas was entitled to an equal share, instead of pro rata. It is my understanding, and I wonder if you could verify it or not, that there are actually 5,000 attorneys and other investigative personnel in State and local enforcement agencies involved in unfair and deceptive advertising across the country.

Mr. OLIVER. That is a number from years ago. That is certainly the ball park figure we had from several years ago; yes.

Mr. CAMPBELL. Very briefly, the individual State boards, to your knowledge, have actually been investigating deceptive practices, have they not?

Mr. OLIVER. That is my understanding.

Mr. CAMPBELL. Is it your understanding that complaints are also being expressed at the Federal Trade Commission?

Mr. OLIVER. Yes.

Mr. CAMPBELL. Last line of inquiry. Your understanding of MEDCAL. Let me say that as I understand the antitrust State action rules, if the States of Kansas, or Oregon, or any other wished to take the Federal antitrust role out, they could do so by State legislation; is that correct, sir?

Mr. OLIVER. There is no question about that. They can do that whether or not it deprives the consumers of their benefits of competition.

Mr. CAMPBELL. Mr. Chairman, in view of the proximity of the vote, I think I must cut my questions off at this point.

Chairman WYDEN. Let me do this, Chairman Oliver. Could we keep Mr. MacLeod and Mr. Zuckerman for a few more minutes and pursue some additional questions?

Mr. CAMPBELL. If I could, while the chairman is here, I have been given something which purports to be recent Federal Trade Commission cases involving health claims, 1983 to the present, which total 43 cases. Might I ask you to verify that is indeed what it purports to be? And then, if the Chair permits, I would like to make it part of the record.

Mr. OLIVER. Yes.

Mr. CAMPBELL. I would like to make part of the record 43 cases that the Federal Trade Commission has been pursuing involving health care claims from 1983 to the present.

Chairman WYDEN. Without objection, so ordered.

[The information may be found in the appendix.]

Chairman WYDEN. Mr. Oliver, I am sorry that the clock cuts off your presence. We do wish you good luck in your future endeavors. With your permission, we will keep Mr. MacLeod and Mr. Zuckerman for a bit longer, and we will excuse you and come back for your associates in a few minutes.

Mr. OLIVER. Thank you, Mr. Chairman, thank you.

[Recess.]

Chairman WYDEN. Gentlemen, let's see if we can get a couple of more minutes in. What I found striking about the testimony of the Oregon representatives was that not only do they disagree with Mr. Oliver on every single point, but they paint an extremely bleak picture about the future.

Dr. Johnston said that "doctors are frustrated and frightened about aggressively policing their own." Now, we were told by Mr. Oliver that the professionals can and do police their own, imposing their own codes of ethics. Who is right on this point?

Mr. **MacLeod**. I think you have testimony from some other witnesses as to societies who do police their own codes of ethics. So, I think there is policing out there. I think the question is whether or not there is a perception that the policing is inadequate or the policing is chilled by antitrust laws.

I think that to the extent that boards or societies feel themselves chilled by the antitrust laws, that is a concern that is unwarranted. There is no provision in the antitrust laws—and, as the chairman testified, there is no provision in the Commission orders—that prevents boards, societies, and associations from adopting legitimate rules that reasonably address deceptive accounts and practices.

Chairman **Wyden**. So, they are just off-base, is what you are saying? It is unwarranted, unjustified, no grounds whatsoever?

Mr. **MacLeod**. I think that you can get antitrust counsel and good and solid antitrust counsel to the effect that you can enforce the rules, and that is what we have heard from the Federal Trade Commission. That is the message we have tried to send.

Mr. Zuckerman has been delivering that message for years, as have his predecessors.

Chairman **Wyden**. Well, I talked to the immediate predecessor, Mr. Pertschuk, right before this hearing. He said what is being pursued today at the Federal Trade Commission was very different from his policy and his thrust.

He said, for example, that he felt that there should be competition. He felt there should be advertising and deregulation, but he said it wasn't his intent that these novel approaches to antitrust laws be developed like we are seeing today, so that you have the States paralyzed in terms of trying to deal with these issues.

So, I know there has been a repeated effort to try to cite the kinds of policies we are seeing today as part of a long legacy at the Federal Trade Commission. But I spoke specifically with Mr. Pertschuk and he basically said that the current FTC took one-half of the equation.

They took the half that called for deregulation, and he felt there was certainly grounds for that, but it is not his position that we take this position on antitrust. I just want the record to state that. Does the gentleman from California have any additional questions?

Mr. **Campbell**. I thank you. Very briefly, I had the pleasure to work with Michael Pertschuk when he was Commissioner, and I think it would be fascinating to have him up here, too. It was he who brought the AMA case. It was under Chairman Pertschuk that the case was brought.

I think if you talk to the American Medical Association, at that time they had words for his actions, of which "unique" and "novel" were the kind of. My question to both of you is very simple. Let me lead you through a series of quick questions, and ask you to amplify any remarks.

The quick questions are, if the States are chilled by antitrust applications by the Federal Trade Commission, is it not within the

States' own power to exempt themselves from the antitrust policies following MEDCAL?

Mr. **Zuckerman**. Yes; it is.

Mr. **MacLeod**. Certainly.

Mr. **Campbell**. If the States are complaining about insufficient activity in the consumer protection area, the States are free to apply their own more rigorous standards for protection; is that not the case, Mr. Zuckerman?

Mr. **MacLeod**. Certainly.

Mr. **Zuckerman**. Yes.

Mr. **Campbell**. The Bureau of Competition has universal jurisdiction. I look at it that way, and finally, to the extent there is a chill, I took the testimony earlier today that neither the Oregon gentleman nor the Kansas gentleman had any specific instance where the Federal Trade Commission contacted him and said, you may not engage in this practice.

Do you know of any instance where you or anyone in your office has contacted individuals in the peer review or State authorities of Kansas, and told them, you may not engage in peer review or may not engage in the disciplining of unfair advertising?

Mr. **Zuckerman**. Not that I was aware, and I was pleased that they did not have any specific examples.

Mr. **MacLeod**. The same holds true for me.

Mr. **Campbell**. I thank the chairman.

In conclusion, it is only fair if there are any points of amplification either of you gentlemen think you could make on behalf of the chairman, than I, for one, would like to hear it?

Mr. **MacLeod**. Thank you.

Chairman **Wyden**. Let me ask you this——

Mr. **Campbell**. Excuse me. I left it as a question mark. I think Mr. Zuckerman is about to respond.

Mr. **Zuckerman**. Yes; I just wanted to make one observation, and I can't remember whether it was the gentleman from Kansas or the gentleman from Oregon who said that here was a dangerous procedure. I think it was referred to as chemical peeling. I guess I was totally baffled.

There is nothing in the antitrust laws or anything in any Federal Trade Commission order or policy that would in any way restrict the State of Kansas from prohibiting any sort of dangerous practice from being engaged in by a doctor or anyone else, if, as a matter of law, this State wished to prohibit that. It seemed to me that they don't have to be worried about, is the advertising truthful or deceptive if the practice is dangerous. They have a power to put a stop to it immediately.

Mr. **Campbell**. Thank you.

Thank you, Mr. Chairman.

Chairman **Wyden**. Gentlemen, I would really urge you to read the testimony from the States of Oregon and Kansas, because it is replete with specific statements about how frightened and fearful they are about going forward and trying to protect the citizens of their own States.

Now, you all seem to have established a standard here. I want to note it for the record. That is that unless you all get on the phone specifically and tell a State not to do something, that somehow you have accomplished your statutory function under the Federal trade statutes. I disagree with that very, very strongly.

You have States here, and there are not just two of them. We feel they are representative of the States in this country that are now, in their own words, almost paralyzed in terms of trying to go forward and bring these actions.

Mr. Oliver defines standards like everyone would have to go to Kansas to consider it a national issue that would be worthy of the Federal Government—that now you all seem to be devising a standard that unless someone at the Federal Trade Commission calls the States of Oregon and Kansas up and says, do not do anything under any circumstances, that you have accomplished your role under the Federal consumer protection statutes.

I think that is unwise. I share the view that I spoke of earlier, that I think that this is a departure from that of your predecessors. I do think they favored competition and favored advertising, but did not support such approaches as yours in the antitrust area, or with respect to interstate corporations.

Unless you all have anything further that you would like to add, I am going to excuse you all. I am going to ask the staff to try to finish the hearing. Mr. Campbell and I have been asked to come to the floor. We are going to leave the record open for any additional comments that you all would like to make, or the Commission, or any individual Commissioner would like to have included, and unless you have anything that you would like to add further, we will excuse you at this time.

Mr. ZUCKERMAN. Thank you, Mr. Chairman.

Mr. CAMPBELL. Mr. Chairman, it has been a real pleasure, I like working with you.

Chairman WYDEN. I think we have to take care of the formalities of swearing our next witness. Ms. Leonard, let me apologize to you. It is obviously without precedent, the activity on the floor. Do you have any objection to being sworn as a witness?

Ms. PEARSON. No, sir.

[Witness sworn.]

Chairman WYDEN. Ms. Pearson, I am going to try to return for your testimony, and I want to apologize to you for the chaotic afternoon that we have had. We are very interested in your views, and I am very aware of the outstanding work that the Women's Health Network has been doing. I am anxious to work with you on this and a variety of other issues.

So, I am going to turn it over to the majority and minority staff and hopefully, I will be able to get back. I do want to apologize to you for the hectic nature of this afternoon's proceedings.

Thank you, again.

Mr. JENNING. [presiding] Ms. Pearson, thanks very much for coming forward. If you wouldn't mind, please summarize your testimony in about 5 minutes.

TESTIMONY OF CYNTHIA PEARSON, PROGRAM DIRECTOR, NATIONAL WOMEN'S HEALTH NETWORK

Ms. PEARSON. As you know, I am Cynthia Pearson, the program director, and I am representing a consumer advocacy group concerned with women's health. So, the questions we have about the issue that the subcommittee is holding hearings on today, are one, can a woman evaluate her need for cosmetic surgery in the current climate of unrestricted advertising.

Can she use advertising to help her find a physician who is competent and qualified to perform the surgery that she thinks she needs? Can she rely on ads or use ads in any way at all in her information-gathering process to find out about cosmetic surgery—what effects it will have, what benefits it will have, and if there is a problem with the care that she receives after choosing to have cosmetic surgery, can she find an effective remedy for her problem?

In the current situation with unregulated advertising of the kind we have seen and the kind I have brought with me, we think the answer is no, and we think that Government intervention is needed.

So, to start off with, I would like to explain why we think that a woman who has been injured by cosmetic surgery can't find an effective remedy herself. I was especially struck to hear one of the members in his opening statement say that malpractice suits are a remedy.

A woman, a lay person will always be viewed as a little bit less credible than a professional with a degree or several degrees, and often a male. So, many women don't have that option as available to them as it should be. Other women who decide to take that option find that because the medical procedure that caused the injury was cosmetic surgery, they are even more diminished or stereotyped as complainers. It is thought to be a trivial matter. Why did they have cosmetic surgery in the first place? They just must always be dissatisfied.

Our Network, because of holding ourselves out as an advocacy group for women's health, receives several thousand requests for information every year. We maintain a clearinghouse of information on women's health.

I deal with a lot of people on the phone myself, and I have talked to women in specifically this situation. One was injured by botched cosmetic surgery. She wanted a remedy that not just recompensed her for the injury, the harm, the pain, the suffering. What would change the care others received? She wanted to make sure that this physician couldn't continue the bad practice that he had been engaging in.

If she decided to file a malpractice suit, it wouldn't necessarily have that effect. So, from the consumer's point of view and from the point of view of a national organization trying to advocate for better health for women, we think that the Government needs to get involved in this.

What are the ways the Government can get involved? We certainly don't want the Government involved in deciding what surgery is needed and what isn't. That is not a decision any of us would like to make for anyone else, although most of us would like to see cosmetic surgery only when it was needed.

But none of us want to play God to decide what is needed and what is not. So, the important place for governmental intervention is in the information-sharing process, both in advertising, medical advertising, and also in the doctor-patient interaction.

The three recommendations we would make are similar to the the Board of Medical Examiners, which you heard at the beginning of the hearings. We would like to see guidelines or standards of what constitutes false and deceptive advertising in the medical realm.

We, from our point of view as consumers, think that some but not all of what should be included in those standards are restrictions on the use of the phrase board certification to the two boards that are part of the system that has been discussed, the specialty boards governed by the American Medical Association.

We would also like to see a prohibition on claims for mental or emotional results in the ads. One of the questions I opened up my summary with was, can a woman use ads to help her evaluate if she needs surgery?

I brought along The Washington Post Health Section, which is great. Isn't it fantastic that we can give average lay people very easy access to health information which is accurate, timely, readable? It is in the level of language most of us read at.

But what is this at the back of the section? These horrible ads, before-and-after pictures. "You will be happy; your self-image will improve; everything will be better." Misleading information about the credentials of the people.

So, as it stands, unregulated to the extent—I know you have heard a lot of disagreement about what kind of regulation is allowed right now or not—but to the extent that these ads can be published, and we have spent time after time, hours and hours writing letters to The Washington Post asking them to stop taking the ads, and as far as the newspaper is concerned, it is commercial speech, there is nothing they can do about it. They need to have ads to bring us the news.

So, it looks to us, from the consumer's point of view, that Government intervention is the appropriate and needed remedy at this point. We would like to suggest, in addition to asking the FTC to promulgate guidelines or standards, we would like to suggest also that there be some uniform consideration of minimum requirements across States for the provision of cosmetic surgery.

We would like to throw it out on the table for discussion. The other thing that we would like to suggest isn't quite as controversial, isn't quite as new, is that there be required for cosmetic surgery as is required in some States already for certain proceedings like hysterectomy and breast treatment, written, confirmed consent.

We would like for the physician to be responsible for providing informed consent for patients' signatures and that the informed consent language not be mandated, of course, because there is freedom of speech between doctors and patients as well, but that there be guidelines that require an explanation of the requirements for board certification, appropriate board certification, and how that physician compares to those requirements.

An explanation of the risks and benefits. The risks should include all risks that have been acknowledged in peer-reviewed journals on that particular procedure, and because these procedures for the majority of people are elective events, a mention of the number of deaths associated with them is appropriate. We would like to see that kind of detail in the written, informed consent.

To close, I just want to refer back to our opinion that Government intervention is needed. Medical malpractice suits are not the answer. It is not a good use of society's resources, and it doesn't make broad change that affects, for the better, the provision of medical services for other people in that community.

Thank you.

[Ms. Pearson and Ms. Zones' joint statement may be found in the appendix.]

Mr. **Jenning**. Thank you, Ms. Pearson, and we will include your written statement for the record. Thank you for your recommendations.

Because of the lateness of the hour and the events of the day, I think it is now appropriate to adjourn this hearing. Thank you all very much for coming.

[Whereupon, at 4:10 p.m., the subcommittee was adjourned.]

APPENDIX

OPENING STATEMENT

THE HONORABLE ELIOT ENGEL
BEFORE THE
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY

MEDICINE'S NEW BACK ALLEY

Mr. Chairman, over the last two years, under your leadership, the subcommittee has invesitgated trends in medicine and how they affect the quality and cost of medical care. None appears to me to be more obvious and more dangerous than the totally unregulated field of cosmetic surgery.

For centuries doctors have quite rightly viewed their profession as a calling, a job with ethical and moral demands placing it above mere issues of dollars-and-cents, profit-and-loss. It is indeed unfortunate, however, that a few bad apples can spoil the barrel, for we have found that most in the medical community are honest and ethical. But, in cosmetic surgery parlors, some have apparently viewed the almightly dollar as the only thing that counts.

Advertising techniques typically used for automobiles, beer and cigarettes -- outright hype and hucksterism -- now pervade the cosmetic surgery business. And it's most obvious in the aesthetic surgery field.

These ads don't serve the legitimate function of informing the public. Instead, they intentionally entice and deceive. They don't enhance the medical marketplace through increased competition, they victimize consumers in a cutthroat free-for-all.

I believe in competition, too, Mr. Chairman. But I think that advertising should give consumers information they need to make informed decisions. But there are two types of ads. There are those that identify doctors' credentials and the services they provide. But there are also those that blatantly seduce the unsophisticated, ads that lure them into the operating room. They give patients an implied warranty of safe, painless and easy surgery that will make them happier and more successful people.

But when the FTC developed its laissez faire policy of anything goes advertising, most surgery was done in hospitals, under the watchful eye of peer review committees. But today, in cosmetic surgery alone, some 95% of the procedures -- hundreds of thousands per year -- are done in outpatient facilities, most of which are not inspected. Many of these pseudo-surgical centers don't meet even minimal quality control standards. Many don't even have basic life support equipment.

Mr. Chairman, I have real problems with the fact that there are no requirements for facilities where doctors do breast implants, tummy tucks, and liposuction. I think that most of my constituents would be surprised too -- especially considering that my home town has almost as many cosmetic surgery parlors as it has delies.

I applaud the Chairman for initiating this investigation, for telling the public about the risks they face, and for bringing the key players together to cure this problem.

Mr. Chairman, I look forward to joining you in introducing legislation to protect the American public from the few doctors who are more concerned about their own pocketbooks than their patients' safety.

ATTACHMENT TO TESTIMONY OF RICHARD GANNON

ELIMINATE LINES, POCKMARKS, WRINKLES, BLEMISHES AND SPOTS WITH OUR NONSURGICAL PROCESS!

PATIENT BEFORE EXODERMOLOGY

Exodermology is performed ONLY BY LICENSED PHYSICIANS. It is a safe, effective, non-surgical procedure which can remove up to twenty years from your appearance.

We can provide Wichita references and show you many unretouched before and after photos of local Exodermology patients.

Call 942-7100 and make an appointment with one of our consultants and find out what Exodermology can do for you.

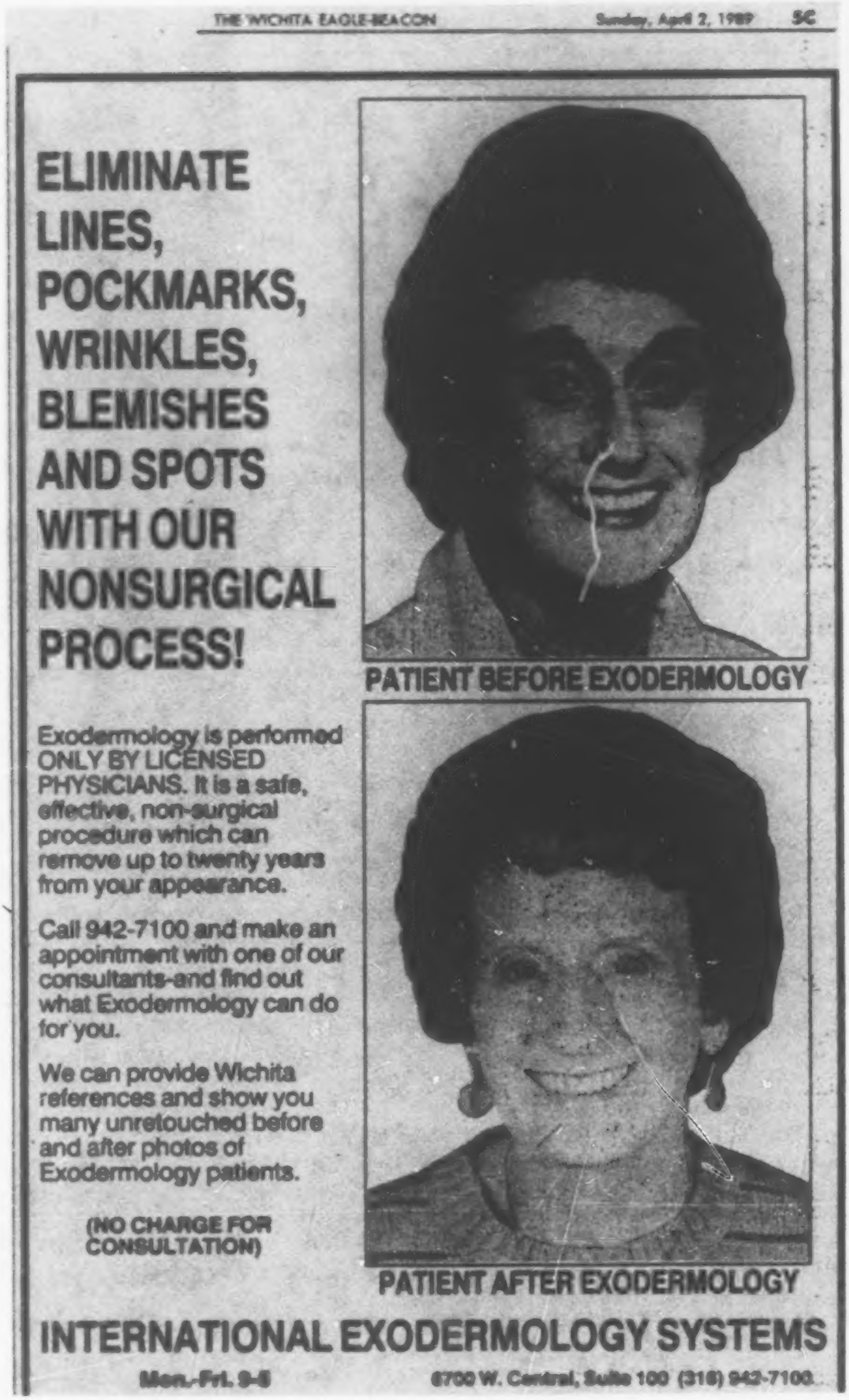
(NO CHARGE FOR CONSULTATION)

PATIENT AFTER EXODERMOLOGY

INTERNATIONAL EXODERMOLOGY SYSTEMS

Mon.-Fri. 9-5

6700 W. Central, Suite 100 (316) 942-7100



THE WICHITA EAGLE-BEACON Sunday, April 2, 1989 5C

ELIMINATE LINES, POCKMARKS, WRINKLES, BLEMISHES AND SPOTS WITH OUR NONSURGICAL PROCESS!

Exodermology is performed ONLY BY LICENSED PHYSICIANS. It is a safe, effective, non-surgical procedure which can remove up to twenty years from your appearance.

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INTERNATIONAL EXODERMOLOGY SYSTEMS

Mon.-Fri. 9-5 6700 W. Central, Suite 100 (316) 942-7100

PREPARED STATEMENT OF DR. HUGH B. JOHNSTON

Board of Medical Examiners

620 CROWN PLAZA, 1500 S.W. FIRST AVENUE, PORTLAND, OR 97201-5826 (503) 229-5770

101st Congress
UNITED STATES HOUSE OF REPRESENTATIVES
Committee on Small Business
Subcommittee on Regulation, Business Opportunities, and Energy
Chairman: Rep. Ron Wyden

I am Dr. Hugh B. Johnston, from Eugene, Oregon. I am specialty certified in the American Board of Internal Medicine, which is a board recognized by the American Board of Medical Specialties. I have been involved in peer review since the late 1960s when I attended the first AMA National Peer Review meeting. In 1980, I was president of Lane County Medical Society. In 1984, I was president of the Oregon Medical Association. I am currently Chairman of the Oregon Board of Medical Examiners, the state regulatory body which licenses and disciplines physicians. I would like to introduce John Ulwelling, who is the Executive Director of the Oregon Board of Medical Examiners. It is certainly our pleasure to appear before this Committee.

I am here to relate my personal experiences with the difficulties physicians have in doing peer review to reduce the cost, and improve the quality, of medical care in the United States.

I am aware that this committee is concentrating on concerns related to cosmetic surgery. I do believe the basic issue is broader than just cosmetic surgery. It seems to me the question is, whether the consuming public can control the activities of health professionals in an unregulated competitive atmosphere, or whether the health professionals can or will regulate themselves for the public good. Can an individual consumer alone determine the quality of care with no assistance from physician peer review groups or regulatory bodies?

I feel the public often is knowledgeable about relative cost, the philosophy of various insurance plans, and in using some citizen guidelines to achieve understanding of profession credentialing. However, much of the public does not understand nor are they able to differentiate among the various medical illnesses with varying physiological and treatment claims promulgated by media advertising. I believe we need a healthy mix of competition and regulation.

Physicians, such as myself, who have been active in the peer review arena feel frustrated and frightened. Voluntarily, often uncompensated, we feel an ethical, professional obligation to do peer review. We think our involvement in peer review serves the public well.

In the last few years, however, we have retreated from participation in peer review, and when we do participate are less than candid in the application of peer review for fear of potential liability issues which are the result of the atmosphere generated by the Federal Trade Commission. We are exceedingly concerned about the antitrust implications of peer review, as well as defamation suits and the possibility of promoting unwarranted medical malpractice actions against colleagues. I feel that we could overcome these risks, as well as the possible antagonism of colleagues when we engage in these pursuits, if we are not subject to being personally crucified with triple damages which our malpractice insurance would not cover.

As a member of Lane County Medical Society, I was on the Professional Standards Committee, which handled patient complaints or disputes regarding physicians. Any complaints which seemed to violate the Medical Practice Act were referred to the Board of Medical Examiners. We were generally effective through gentle persuasion in changing physician behavior, and we were a good resource to the community to check the most serious abuses. I thought that our most outstanding actions were in improving communications between physicians and their patients. In 1987 the committee was disbanded because the Medical Society could not get liability insurance. Further, we felt that we could no longer afford the possibility of the cost of a Federal Trade Commission investigation, even if our actions were well-meaning.

When I was President of the Oregon Medical Association, we had two committees that focused on peer review and fee complaints. The Peer Review Committee still functions, though it is less active. The Board of Medical Examiners still occasionally uses this review group to help investigate certain technical areas. The degree of activity of this group now is best exemplified by the fact that in my four years on the Board of Medical Examiners, the Board has not received a single complaint from this Peer Review Committee for possible violations of the Medical Practice Act while, heretofore, there were several cases a year.

The Fee Committee of the Oregon Medical Association served to handle concerns from the public as well as insurance companies with regard to excessive fees. The committee was empowered to recommend a fee reduction to an insurance company and caused many a physician to reduce a fee to a citizen since we were willing to go to court to testify for the public against the physician. Over 90% of the time fees that were questioned were rolled back. Unfortunately, when the Federal Trade Committee activity started, we disbanded the committee and attempted to develop guidelines with the Federal Trade Commission on our processes. After a year of complicated written correspondence, we decided the committee could not function since any activity would be judged as too risky. In other words, we never felt we could get from the Federal Trade Commission exactly what we could do or could not do.

Currently, I am Chairman of the Board of Medical Examiners. The Board is now in its 100th year, and is recognized as being on the cutting edge of discipline, and is certainly not shy about tackling controversial issues. But in the present "competition only atmosphere" that has been promulgated by the FTC, the Board has avoided fee problems and issues of advertising for the most part because it is uncertain as to what it can do legally. The Board has too much to do to be burdened with a costly, time-consuming battle with the Federal Trade Commission or individual litigation regarding advertising or fees. The State of Oregon does have a Doctors Title Law which directs all practitioners of healing arts to properly identify themselves, i.e., medical doctor, doctor of osteopathy, chiropractor, etc.

The Board has been able to discipline some physicians who have excessively charged since it has been able to show that these physicians are grossly overutilizing, and this, of course, is inappropriate practice, and in violation of the Oregon Medical Practice Act. Furthermore, the Board has recently promulgated a rule stating that physicians cannot label themselves "board certified" by a specialty board unless that board is recognized by the American Board of Medical Specialties. Nevertheless, we are still constrained from restricting self-designated "experts" who spend health resources on advertising that they are the "best of everything." These physicians offer procedural panaceas in their unsupervised office, with seemingly questionably trained assistants. They promote the use of elective procedures without informing the public of any risk. These physicians are weekend wonders who are trained under a franchise that will teach marketing and advertising with some technical training. They generally have no formal training or special credentials in the area of the body they attack with their advertised new procedure they have just learned over a weekend. They are drawn to this endeavor because of the money which can be made in this competitive, unregulated milieu.

The Oregon Board has recently revoked the license of a physician who was a franchise physician doing face peels. He killed an elderly lady whose post operative care was entrusted to an untrained person in a local motel. This gross negligence was covered by our Medical Practice Act. But we function on a case-to-case system and have to sit idly by watching others of the same ilk until they damage a patient and we get a complaint. Currently a general practitioner comes 100 miles to contact people in a local hotel, in my community, promoting, via advertising, face peels, which he provides out of his office in a small community in Southern Oregon. All the Board of Medical Examiners can do at present is wait for the injury.

I am here relating my own personal experiences and views. My suggestions do not represent the official position of the Oregon Board of Medical Examiners or any other organization. It is my view that the following should be accomplished:

1. Physicians' offices, emergency care centers, etc., who do significant outpatient procedures should be required to be accredited by somebody such as the Joint Commission for the Accreditation of Health Organizations. Our 'Short Stay Unit' in Eugene is connected to the hospital, and thus is inspected by the Joint Commission, but other out-of-hospital facilities are not licensed or investigated.

2. Public statements about board certification should be restricted to those boards approved of by the American Board of Medical Specialties (ABMS), as stated in the Oregon proposed administrative rule.

3. It should be required that individuals who do a medical procedure in the office setting have privileges to do the same procedure in their local hospital. I recognize that is a very delicate area with antitrust implications. There would obviously need to be some way to open up credentialing to physicians who are not on a hospital staff but are well trained. I would suggest this be accomplished by some statewide credentialing body. There would also have to be some mechanism to allow professional training in offices and hospitals for physicians to learn new procedures. I believe this could be accomplished by the same credentialing body mentioned above. I am not sure whether it is easier to enforce this credentialing restriction through payment restriction or through professional regulation.

4. I think it is necessary to force the Federal Trade Commission to address the issue of allowing peer review by professional medical societies. We need guidelines that allow local physician groups to police their brethren as long as it is done for quality considerations. Further, the Federal Trade Commission should allow national professional bodies that are recognized by the American Board of Medical Specialties, to issue standards and guidelines for treatment. This would be educational for the public as well as the profession. As it stands now, someone can make an advertising claim, and no one dares refute this statement because of possible liability. I believe that currently

the public is left without the necessary resources to make their decisions.

5. I feel it is necessary to make the commitment to regulate advertising in the medical field. It should not be "buyer beware" in an area in which the buyer has no expertise. As starters, I would suggest that these rules eliminate personal testimony, prohibit unproven claims or statements, and that advertising should avoid statements that encourage use of procedures that are not always necessary. (Certainly not everybody needs a radial keratotomy.) Further, I believe that all advertising promoting medical procedures should at least list some information about complications. In other words, advertising should inform and not just promote. To place teeth in this, I would suggest that any violations result in a fine and a significant public retraction for false and misleading statements.

As stated before, I am aware that this body is concentrating on cosmetic surgery. But I believe the issue is bigger. Laser experts and other techniques are just starting to be advertised. They can be appropriately used, of course, but also abused by ill-trained or overutilizing physicians. The public needs assistance in the information arena and professionals need peer review methods to keep entrepreneur or buccaneer physicians in line. The Federal Trade Commission in its haste to eliminate the "good old boys" anti-competitive network has left the public bare to misinformation and misued technology. Competition without some regulation is returning us to the era of snake oil. There are many physicians who serve on licensing bodies, credentials committees and other peer review groups, who are willing to assist in performing their state and professional obligations. We specifically need guidelines and a methodology so that we can accomplish worthwhile peer review.

Thank you for allowing me time to present my views regarding these issues.

NATIONAL WOMEN'S HEALTH NETWORK

STATEMENT ON COSMETIC SURGERY REGULATION

HOUSE SMALL BUSINESS SUBCOMMITTEE ON REGULATION

JANE SPRAGUE ZONES AND CYNTHIA PEARSON

May 31, 1989

Mr. Chairman and members of the Committee, thank you for the opportunity to testify today. We applaud the work of the Subcommittee in addressing possible regulatory interventions to create a safer and more effective situation for women seeking cosmetic surgery. It is very important for a Congressional Committee to deal with the issue of fraudulent and deceptive advertising. Often, women who are victims of negligent and inadequate medical treatment for cosmetic surgery are unable to instigate professional review of offending physicians. Nor are they taken seriously when they do complain.

The National Women's Health Network is the only national advocacy organization concerned solely with women's health issues. We maintain a Women's Health Clearinghouse and respond to several thousand requests for information each year. I remember talking to one woman on the phone who was suffering from botched cosmetic surgery. She wanted to do something to prevent this from happening to other women in her community. She was not only interested in recompense for her personal injury. But she felt stymied by the reactions of others who were almost contemptuous of her injuries. She told me of reactions such as "Well, what do you expect if you get involved with plastic surgery."

Many of us might wish that cosmetic surgery was done only for people who truly needed it, people suffering from burns, accidents, or birth defects. But none of us would like to be responsible for deciding which surgery was needed and which was being done for vanity. So cosmetic surgery must continue as it is now, with patients deciding for themselves what surgery they need.

We believe that many women choose cosmetic surgery based upon supply-driven advertising designed to "repair" socially created feelings of inadequacy about their appearance. I have brought with me a few copies of the Health Section from the Washington Post. The Post set a wonderful example for other newspapers by being one of the first daily papers to establish a Health Section. It is a very useful source of information about daily health habits, new treatments, and common conditions. We suggest women read it and often reproduce articles from it for people requesting information from our clearinghouse.

It is appalling that in this same section of the paper are misleading, exploitative advertisements for cosmetic surgery. These advertisements make claims not only about the physical results of cosmetic surgery, but also about how you will feel about yourself. They imply accreditation by so-called specialty Boards that mean nothing. The advertisements promote an extremely limited vision of beauty. How can anyone make an honest decision about whether or not they need cosmetic surgery when they are exposed to advertisements like these week after week?

We recommend that the Subcommittee consider three avenues of intervention.

Request that the Federal Trade Commission establish regulations governing medical advertising. The regulations should include a prohibition on language that promises you will feel better about yourself. The regulations should also disallow the use of the terms "Board" or "Board Certified" or "Board Certification" to describe physician qualifications unless the Board reference is to one of the specialty Boards governed by the American Medical Association.

Consider requiring uniform minimum requirements for the performance of cosmetic surgery in all states, including possibly a graduate residency requirement in general surgery.

Require, as has been done by certain states for procedures such as hysterectomy and breast cancer treatment, that all physicians performing cosmetic surgery provide an informed consent statement for potential patients' signature. The statement should detail the requirements for Board certification in Plastic and Reconstructive Surgery (or in Otolaryngology if it is a head or neck procedure), and the providing physician's qualifications relative to those of Board Certified Plastic Surgeons. The informed consent statement should also include a written statement detailing the benefits and risks of the procedure being performed. The risks should include all risks that have been reported in peer-reviewed medical journals and the total number of deaths known to be associated with that type of cosmetic surgery.

To close, I would like to remind the members of the Subcommittee of the importance of government action. Currently, the only remedy available to a person injured by cosmetic surgery is a malpractice suit. That is neither effective in making broad change, nor is it an efficient use of society's resources. The problem is fueled by false and deceptive advertising and it will not be remedied unless medical advertising is regulated.

May 1989

Recent Federal Trade Commission Cases Involving Health Claims

1983 - present

Orders or Complaints Issued

North American Philips Corp. and McCaffrey and McCall Inc. Black man's shaver which will cure "razor bumps." 3/7/83

Braswell Inc. Baldness prevention and cure. 9/14/83

Spinal Health Services Inc. Laser facelifts. 10/13/83

Emergency Devices Inc. and Monte Proulx. Emergency escape mask which does not filter carbon monoxide. 11/3/83

Estee Corp. Special health-related foods appropriate for diabetics. 11/16/83

PharmTech Research Inc. Food supplement for reducing the risk of some forms of cancer. 5/1/84

Acu-Form Weight Control Centers Inc. and Thomas A. Dardas. Ear mold weight reduction product and clinic. 10/1/84

Biopractic Group Inc. Mineral ice to reduce pain and inflammation arising from muscle sprains, arthritis, and rheumatism. 12/24/84

A & A Laboratory Inc. Hair analysis testing service to measure mineral deficiencies and excesses. 2/25/85

Rush-Hampton Industries Inc. and Young & Rubicam/Zemp. Table-top air cleaner to eliminate tobacco smoke, formaldehyde, pollen, and dust. 4/29/85

Descent Control Inc. Safety device for individuals working on or descending from tall buildings. 4/29/85

P. Leiner Nutritional Products Corp. Wheat germ oil to improve endurance, stamina, vigor, and overall athletic performance or physical fitness. 5/3/85

Associated Mills Inc. Table-top air cleaner to eliminate tobacco smoke, formaldehye, dust, and pollen. 7/23/85

North American Philips Corp. Table-top air cleaner to eliminate tobacco smoke, dust, pollen, and other indoor pollutants. 2/10/86

Sunbeam Corp. Table-top air cleaner to eliminate tobacco smoke, formaldehyde, and other indoor pollutants. 2/11/86

William B. Jones. Mouthwash which will sober persons who have consumed large amounts of alcohol. 2/19/86

Intra-Medic Formulations Inc. Weight control and baldness-cure products. 2/28/86

R.J. Reynolds Tobacco Co. Major government-funded study tends to refute theory that smoking causes heart disease. Complaint issued 6/16/86.

Meadow Fresh Farms Inc. (Roy and Larry Brog). Dry milk substitute for reduction of cardiovascular disease. 7/15/86

Weider Health and Fitness Inc. and Joseph Weider. Two nutrient supplements to increase muscularity and strength. 12/11/86

Viobin Corp. Wheat germ oil to improve physical fitness or performance. 12/17/86

Aquanautics Corp. Marine survival suit with potentially life-threatening safety defect. 2/17/87

Figgie International Inc. Fire alarm system combining heat and smoke detectors which does not provide greater protection from hot, flaming fires than smoke detectors alone. 4/21/87

Kraft Inc. Kraft Singles cheese slices contain as much calcium as five ounces of milk and more calcium than do most imitation slices. Complaint issued 6/1987.

Buckingham Productions Inc. and Dr. Barry Bricklin. Weight reduction plans and products. 7/30/87

Puritan-Bennett Aero Systems Co. Fire-and-smoke-protection mask which does not filter carbon monoxide. 8/25/87

Jerome Milton Inc. Toothpaste which cures gum disease and reduces plaque. 10/26/87

New Medical Techniques Inc. Countertop water distiller which fails to remove potentially carcinogenic volatile organic chemicals. 11/18/87

Great Earth International Inc. Food supplement for weight reduction, muscle building, and promotion of healing. 3/15/88

Philip Goutell, Frank E. Bush, and Conceptual Trends Inc. Sex nutrient pills. 4/12/88

The Silver Group. Artificial tanning device which tans without the risk of skin damage or aging. 4/13/88

Sun Industries Inc. Artificial tanning device which tans without the risk of skin damage and can be used without eye protection. 5/13/88

Kingsbridge Media & Marketing Inc. Weight reduction pills. 6/7/88

North American Philips Corp. Tap water filter which adds a suspected carcinogen to the water. 10/24/88

Removatron International Corp. High-frequency, tweezer-type devices for permanent hair removal. 11/4/88

California Pacific Research Inc. Baldness preventative and remedy. Complaint filed 11/14/88.

Pantron I. Baldness preventative and remedy. Complaint filed 11/14/88.

Campbell Soup Co. Low-fat and low-cholesterol soups reduce risk of heart disease. Complaint issued 1/26/89.

General Nutrition Inc. Food supplement for reducing the risk of some forms of cancer. 2/2/89

Body by Design and Donald and Dinah Simioni. Electric muscle stimilation that produces the same effects as exercise. Complaint issued 3/17/89.

Associated Mills Inc. Water treatment appliance which does not remove certain hazardous organic chemicals. 4/27/89

An-Mar International Ltd. Inc. and Andrew and Marzenna Bobel. Suntanning devices that produce health benefits and do not pose a risk of harmful side effects such as skin cancer, and do not require protective eyewear. Consent agreement subject to final approval. 5/9/89

Reproductive Genetic Health Center Ltd. and Dr. Cecil B. Jacobson. Likelihood that Jacobson's infertility treatments would result in pregnancy or that the patient is actually pregnant. Up to $250,000 in consumer redress. 5/18/89.

N. OREGON
IAN
W YORK
IRY, VIRGINIA
A, VIRGINIA
HAEL R. MCNULTY, NEW YORK

101st Congress
United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, DC 20515

MINORITY MEMBERS
WM. S. BROOMFIELD, MICHIGAN
LARRY COMBEST, TEXAS
MELTON D. HANCOCK, MISSOURI

STEVE JENNING
SUBCOMMITTEE STAFF DIRECTOR
[illegible]

ANDREW POWELL
MINORITY SUBCOMMITTEE PROFESSIONAL
STAFF MEMBER
[illegible]

May 10, 1989

Dr. Frank James Kutilek
International Exodermology Systems
5700 West Central
Suite 100
Wichita, Kansas 67212

Dear Dr. Kutilek:

Pursuant to the rules of the U. S. House of Representatives, the Subcommittee on Regulation, Business Opportunities and Energy of the Small Business Committee is extremely interested in the current explosion of cosmetic procedures being performed nationwide. Based on the information gathered by the subcommittee over the last six months and testimony before the subcommittee on April 4, 1989, it appears that in many cases cosmetic surgery is being performed by less than fully qualified doctors and in many cases at totally inadequate facilities.

The subcommittee is particularly concerned that the consumer is being inundated with some doctors' false and deceptive advertising that preys on people's insecurities, prompting them to have potentially dangerous, costly and unnecessary cosmetic surgery procedures. Additionally, we are concerned that many potentially unqualified physicians are tempted to perform procedures for which they have little or no training through promises of dramatically increased profits for their medical business.

During the course of its investigation, the subcommittee has become aware of your medical training and marketing programs. Given the subcommittee's efforts to assess what is fueling the unprecedented growth of this medical field and what the resulting public health risks may be, I directed my staff to interview you in Wichita. That interview was to address your relationship with Medical Marketing Services, Inc., and the most basic questions regarding International Exodermology Systems and, out of fairness, to offer you the opportunity to respond to concerns about your specific programs. In addition, I directed the staff to make a routine request for background information on your programs to enable the subcommittee to fully review complaints against practices such as yours and to examine the role your enterprise may play in the rapid growth of this industry.

I was disappointed to learn that you refused to respond to the majority of the staff's questions regarding even the most basic elements of your practice. I want to make it perfectly clear that subcommittee staff is continuing this investigation specifically at the subcommittee's behest. The subcommittee's record strongly suggests that there are serious ramifications for public health policy represented by medical training and marketing programs such as yours.

As chairman of this subcommittee, therefore, I hereby request that you provide answers to the following questions, and the following documents, by close of business on Wednesday, May 17, 1989:

-- What is International Exodermology Systems?

-- What trademarked, patented or otherwise proprietary service, technique or product serves as the basis of your commercial venture?

-- What is the relationship between International Exodermology Systems and Medical Marketing Services, Inc., and/or Mr. Michael Walerstein of Plantation, Florida?

-- Your solicitation letter describes Exodermology as "the most advanced form of chemexfoliation." Are you familiar with Endodermology, a "non-surgical face lift", that is taught and marketed by Mr. Walerstein? If so, how do the two processes differ?

-- The medical and marketing claims made by both your company and that of Mr. Walenstein appear to be quite similar. Did you develop the process of Exodermology and the advertising program you use to market it to both physicians and potential patients? If not, who taught you how to do the procedure?

-- What is your relationship to Ronald Bennett, an alleged doctor who has been affiliated with Mr. Walerstein and others in the teaching and marketing of Endodermology, Exodermology and other similar chemical peels?

-- Your advertisements claim that Exodermology is "a safe, reliable and effective method which can remove up to twenty years from your appearance without surgery." Has the procedure been proven "safe" by the "23 year study establishing the benefits of the treatment"?

-- How long have you been performing Exodermology and upon how many patients have you done the procedure?

-- What do you charge patients for the procedure?

-- How long have you been teaching Exodermology and your marketing procedures to physicians and how many doctors have you taught?

-- What do you charge physicians for your training programs?

-- You claim that Exodermology can generate "GREAT MONEY" for physicians. Specifically, you suggest that, "2 patients a week (and you should average more) can bring you NET PROFITS of more than $200,000 per year." To whom do you market your training programs, how do you market them and what qualifications do you require of those physicians you train?

-- names and locations of your clients employing your marketing services;

-- any and all safety studies conducted on Exodermology;

-- copies of any and all marketing materials you provide your clients;

-- copies of any and all medical training materials, manuals, policies and procedures provided your physician clients;

-- copies of any and all materials you provide patients on Exodermology;

-- an organizational chart and list of all officials employed by International Exodermology Systems;

Page Four

-- a list of all subcontractors employed by International Exodermology Systems;

-- a copy of International Exodermology Systems' incorporating documents.

Should you have any questions regarding this request, please contact Frank Papineau or D.Ann Murphy of the subcommittee staff at (202) 225-7797.

Sincerely,

Ron Wyden

RON WYDEN
Chairman

McMASTER & McMASTER
ATTORNEYS AT LAW
320 SOUTH TOPEKA
WICHITA, KANSAS 67202-4309

FRANK C. McMASTER
D. LEE McMASTER
KEVIN M. McMASTER

(316) 263-4881

May 15, 1989

The Honorable Ron Wyden
United States Representative
United States House of Representatives
363 Rayburn House Office Building
Washington, D.C. 20515

CERTIFIED MAIL - RESTRICTED DELIVERY

Re: Doctor Frank J. Kutilek, III
Your Letter Dated May 10, 1989

Dear Representative Wyden:

This is to acknowledge receipt of your letter addressed to our client, Doctor Kutilek. Such letter has been referred to us for response. We wish to advise as follows:

Several days prior to May 3, 1989, a telephone call was received by our office from a Mr. Frank Papineau. Mr. Papineau advised that he was with your office. He further advised that he desired to meet with the two doctor Kutileks to discuss their relationship with Medical Marketing Services, Inc., which company was located within the State of Florida. Mr. Papineau further advised that he received our name from a news reporter for a Kansas City, Missouri, newspaper. He further advised that he was going to be in Wichita and desired to meet with Doctors Kutilek. When the attorney in our office to whom Mr. Papineau was speaking began asking a series of questions he was advised that if the Doctors Kutilek did not meet and discuss their relationship with Medical Marketing Services, Inc. with him when he was in Wichita on May 3, 1989, that the doctors would be subpoenaed to appear before your committee. I was advised that this statement was made in the context of a "threat" to encourage compliance with his request for May 3rd.

Contact was made with our clients and they agreed, upon our recommendation, to meet with your investigator.

On May 2, 1989, Mr. Papineau called and the undersigned spoke with him. The conversation was pleasant and we confirmed that Doctors Kutilek would be available but would rather not take the time from their busy practice unless it was absolutely necessary. We then advised Mr. Papineau that they knew absolutely nothing about "Medical Marketing Services, Inc." We advised to what extend Doctors Kutilek had made contact with Medical Marketing Services and they did not like what they saw so they left. Your investigator continued to persist in his desire to speak with them and further stated he would like to talk to them in a preliminary way about the activities in which they were engaged. From the verbiage utilized by your investigator, it appeared that he was referring to "exodermology" and that Mr. Papineau was aware of the interest of the State of Kansas, through its Board of Healing Arts, in that activity. With this revelation from your investigator we advised that indeed there was some ongoing litigation between the Kutileks and the Kansas Healing Arts Board. Because of the litigation and the hope for early resolution thereof Doctors Kutilek were not in a position to discuss their business because of possible repercussions as a result of such discussion. We further reminded Mr. Papineau that his request made several days prior had related only to Medical Marketing Services, Inc. Mr. Papineau then indicated that his only inquiry regarding our clients and exodermology would be very limited and inquiry would only go to the extent to see if there was any connection known by Doctors Kutilek between exodermology and Medical Marketing Services, Inc. We again advised your investigator that there was no connection between the Kutileks and Medical Marketing Services, Inc. Mr. Papineau still insisted upon talking with our clients. A time and location (our office) was agreed upon for May 3rd.

At no time were Doctors Kutilek or their counsel advised that any complaints had been made of practices such as Doctors' Kutilek. Also, no mention was made that there was any "concern about Doctors Kutileks' specific program." Your letter of May 10th delineating this is indeed a surprise. We would be interested to ascertain just what complaints have been made, to whom, whether it is exodermology and any additional data which might be pertinent. We would also appreciate being advised of the "concerns" about Doctor Kutileks' program.

The first complete paragraph on page 2 of your letter indicated that you were advised that Doctors Kutilek "refused to respond to the majority of the staff's questions regarding even the most basic elements of your practice." For your information, a large number of responses were given to your "staff." In our opinion, more answers were given than were required to provide information concerning the "basic elements" of the Kutileks' practice. The entire interview was videotaped and the questions, answers, comments, etc. recorded. A copy of this videotape will be made, at your expense, and forwarded to you if you so desire.

The second paragraph on page 1 of your letter further indicates that you question the medical training of our clients. This simply is not the case. We would appreciate it if you would advise us regarding the questions concerning our clients' medical training or background. If in writing, we would appreciate copies thereof and all data connected therewith.

At the time of the interview on May 3rd, your "staff" indicated that Doctors Kutilek were not a specific or named target of your committee. In fact, the investigator implied that he had just learned of the Kutileks' name. Again, the first complete paragraph on page 2 of your letter implies that the subcommittee has directed that an ongoing investigation be made of Doctors Kutilek. We would appreciate it if you would send us the minutes or other written evidences of the meeting of your committee which indicates that Doctors Kutilek were indeed named targets.

Your letter requests that Doctors Kutilek supply you with a myriad of information on or before May 17, 1989. Doctors Kutilek have already taken time away from their practice of medicine in order to meet with your "staff" and then be subject to your letter of May 10th. The time given them is inordinately short. No offer is made by way of compensation to them for the loss of time and expense in order to accumulate the information for you. On the other hand, our clients recognize that your committee may have a legitimate concern about medical practices and deception, particularly in the field of cosmetic surgery. Doctors Kutilek also recognize that you may not be receiving full and complete information concerning their past cooperation and the treatment afforded them. We have therefore been directed to supply you with the following information, which may be somewhat incomplete, but is the best that can be accomplished within the time frame outlined in your letter. The following sets forth each question and the response thereto:

1. What is International Exodermology Systems?

   This was answered and described to two of your staff members on May 3, 1989.

2. What trademarked, patented or otherwise proprietary service, technique or product serves as a basis of your commercial venture?

   See attached Exhibits "A." This was promised to you by us on behalf of Doctors Kutilek at the time of the interview on May 3rd. The exact terms of the contract are proprietary information and, we feel, would be detrimental to our clients' business if disclosed. If a protective agreement could be worked out between your committee and the Kutileks the doctors would be happy to allow a detailed examination of the document. Such protective agreement would, however, have to insure that the contents thereof would never be made public or disclosed to any other person or organization without the express approval of our clients.

3. What is the relationship between International Exodermology Systems and Medical Marketing Services, Inc. and/or Mr. Michael Walerstein of Plantation, Florida?

   This, too, was answered in the May 3, 1989, interview. We can again advise that there is no relationship.

4. Your solicitation letter describes exodermology as the "most advanced form of chemexfoliation." Are you familiar with

endodermology, a "non-surgical face lift," that is taught and marketed by Mr. Walerstein? If so, how do the two processes differ?

This was also answered in the interview on May 3rd. Doctors Kutilek are not familiar with endodermology that is taught and marketed by Mr. Walerstein.

5. The medical and marketing claims made by both your company and that of Mr. Walerstein appear to be quite similar. Did you develop the process of Exodermology and the advertising program you use to market it to both physicians and potential patients? If not, who taught you how to do the procedure?

   The last question was covered in the May 3rd interview. The answer to the first question is "no." To repeat, Mr. or Doctor Bennett taught us the procedure.

6. What is your relationship to Ron Bennett, an alleged doctor who has been affiliated with Mr. Walerstein and others in the teaching and marketing of exodermology, endodermology, and other similar chemical peels?

   This was answered at the time of the May 3rd interview. We have no relationship with them at this time other than a contractual right to insist upon advice or consultation.

7. Your advertisements claim that exodermology is a "safe, reliable and effective method which can remove up to 20 years from your appearance without surgery." Has this procedure been proven "safe" by the "23 year study establishing the benefits of the treatment?"

We were advised by Bennett and several physicians who have worked with the process who stated that there were no problems. Contact Bennett for specifics.

8. How long have you been performing exodermology and upon how many patients have you done the procedure?

   This was answered at the May 3rd interview. We have engaged in the performance of exodermology since July of 1988. We have performed the procedure on approximately 30 to 35 patients.

9. What do you charge patients for the procedure?

   This has also been answered at the May 3rd interview. The cost varies depending upon what has to be done.

10. How long have you been teaching exodermology and your marketing procedures to physicians and how many doctors have you taught?

    We have offered to teach the procedure since December of 1988. We have taught one physician.

11. What do you charge physicians for your training programs?

    This is proprietary information. Such information will only be revealed if an agreement to protect the proprietary nature is agreed upon.

12. You claim that exodermology can generate "Great Money" for physicians. Specifically, you suggest that, "two patients a week (and you should average more) can bring you net profits of more than $200,000.00 per year." To whom do you

market your training programs, how do you market them and what qualifications do you require of those physicians you train?

We market to physicians. We market by direct mail and, if a response thereto, personal contact. Physicians must be regularly licensed and practicing physicians holding an M.D. or D.O. degree from a recognized medical school.

13. Names and locations of your clients employing your marketing services.

None.

14. Any and all safety studies conducted on exodermology.

Contact Bennett (1220 zmsnninh Sbrnur, Spstymrny z33, Los Angeles, California 90024; phone number 1-213-475-9511) and see medical literature that is in existence.

15. Copies of any and all marketing materials you provide your clients.

Basically, none. I gave a copy of a brochure we utilize and an example of newspaper ads we use to the one physician that we trained.

16. Copies of any and all medical training materials, manuals, policies and procedures provided your physician clients.

Proprietary information is contained throughout our manuals. We will release only if nondisclosure agreement is signed.

17. Copies of any and all materials you provide patients on Exodermology.

    See attached.

18. An organizational chart and list of all officials employed by International Exodermology Systems.

    International Exodermology Systems is merely an extension of our office practice. There is no organizational chart or officials. We utilize employees only.

19. A list of all subcontractors employed by International Exodermology Systems.

    Joe Brown.

20. A copy of International Exodermology Systems incorporating documents.

    Not incorporated.

Clients are concerned that there may be some physicians who, by training of activity, are not performing quality and safe facial rejuvination procedures. They agree that if such exists it should be corrected. Doctors Kutilek would be willing to discuss all aspets of exodermology with your committee if:

(1) Non disclosure agreements are approved;

(2) Financial renumeration is agreed for expenses and loss of income for:

    a. Preparation of information;

    b. Travel expenses for physicans and their counsel;

    c. Compensation for physicians for time away from practice;

d. Compensation for physicans' attorneys;

e. Sufficient notice for agreed time for meeting so that patient schedules can be rearranged.

Very truly yours,

McMASTER & McMASTER

F. C. McMaster

FCM/jb
Enclosures

■ Deaths, *Page B-3*
■ TV, *Page B-6*

Mid-America

Monday, April 17, 1989

The Kansas City Times

'Peel' physicians fight state censure

By Sean Hillen
Of the Metropolitan Staff

TOPEKA — In eye-catching ads with headlines such as, "Mirror, mirror on the wall, 20 years are about to fall," two Wichita doctors say that they can remove facial wrinkles and blemishes and make patients look up to 20 years younger in just eight days.

But the Kansas Board of Healing Arts, which monitors doctors in the state, considers the claims too good to be true and has publicly censured the doctors for misleading advertising.

Now the board and the two doctors, Dr. Frank J. Kutilek III and his father, Dr. Frank James Kutilek, have become embroiled in an administrative and legal battle to settle the issue. On Saturday the doctors asked for a review of the censure, marking another round in what officials say could be a long, drawn-out fight.

A public censure is one of the most lenient punishments the board metes out to doctors who fail to meet its standards. If unacceptable behavior continues, the board can place a doctor on probation or revoke his license.

■ A public censure is one of the most lenient punishments the board metes out to doctors. The board can place a doctor on probation or revoke his license.

The controversy focuses on an unusual procedure known as exodermology, in which chemicals peel away the outer layers of skin on a patient's face.

The two doctors claim in their ads that exodermology is "the most exciting youth enhancing medical technique ever conceived" and say it is "a safe, reliable and completely effective method that removes 5, 10 or even 20 years from your appearance."

Some of the ads encourage potential patients with the words, "Your Second Chance To Make A First Impression."

One exodermology treatment costs about $3,500, according to a brochure produced by International Exodermology Systems in Wichita, which is owned by the Kutileks.

The brochure, which is distributed to doctors, also states that a doctor performing the procedure could earn a net profit for a six-month period of $102,360 and a net profit of $250,560 after one year.

"The results promised through these procedures seem a little far-fetched, and we want to put an end to any deception," Richard Gannon, executive director of the Kansas Board of Healing Arts, said Saturday. "We simply cannot allow doctors to make these kinds of claims."

Gannon said the board had publicly censured the two doctors for the ads in February.

The ads have appeared in Kansas newspapers and are often accompanied by "before" and "after" photographs showing patients who have undergone the treatment.

Gannon said the two doctors had not even treated some of the patients shown in the ads.

In a telephone interview Sunday, Steven Smith, a lawyer for the Kutileks, said some of the patients in the ads had not been treated by his clients.

In interviews Saturday, the doctors said that they had treated about 100 patients since they began performing exodermology last July.

"It is an excellent procedure, and I fail to understand why the board is taking this stand," Frank J. Kutilek III said.

The doctors have sued the board, saying that the public censure violated the state's Administrative Procedures Act.

"We are asking the court to reverse the decision," Smith said. "The board took action without giving the doctors a chance to defend themselves. The action harmed the reputation of my clients."

The board has filed a motion to dismiss the suit.

BEFORE THE KANSAS STATE BOARD OF HEALING ARTS

In the Matter of the
Order of Public Censure
Frank J. Kutilek, M.D.
Kansas License Number 11240

ORDER OF PUBLIC CENSURE

NOW, on this 11th day of February, 1989, this matter comes on for hearing before the Kansas State Board of Healing Arts, (hereinafter referred to as "Board") pursuant to the provisions of K.S.A. 1988 Supp. 77-538 for public censure of Licensee.

After reviewing investigative files and hearing statements and arguments of Licensee and being otherwise duly advised in the premises, the Board finds as follows:

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. That, Licensee was originally granted license number 11240 on June 15, 1957 to practice medicine and surgery in the State of Kansas.

2. That, on January 27, 1989, Licensee appeared before Richard G. Gannon, Executive Secretary of the Board, acting for the Board, and two doctors of medicine acting as consultants for the Board.

3. That, on February 9, 1989, the Medicine and Surgery Review Committee met and reviewed information concerning advertisements regarding the procedure known as exodermology.

4. That, on February 11, 1989, the full Board met to discuss allegations and statements concerning Licensee's advertising practices regarding the procedure known as exodermology, pursuant to K.S.A. 1988 Supp. 65-2837(c) and (d).

5. That, certain advertisements regarding the procedure known as exodermology were reviewed by the full Board.

6. That, certain of these advertisements were available for patients of Licensee in the office of Licensee.

7. That, these same advertisements contained photographs of persons, not patients of Licensee, captioned "before" and "8 days later".

8. That, these same advertisements contained the language, "Miracles...In Just 8 Days...Are Our Stock and Trade".

9. That, certain advertisements containing photographs of persons, not patients of Licensee, appeared in a Wichita, Kansas newspaper captioned "Before" and "8 Days Later" and "Look Young Again in Just 8 Days."

10. That, these same advertisements appeared on more than one occasion.

11. That, by the use of said photographs and captions in his office and in a newspaper regarding the procedure known as exodermology, Licensee utilized false, misleading or deceptive advertising which may have violated one or more of the following:

a. That, Licensee has committed an act of unprofessional conduct contrary to K.S.A. 1988 Supp. 65-2836(b).

b. That, Licensee has used false advertisements contrary to K.S.A. 1988 Supp. 65-2836(d).

c. That, Licensee has solicited professional patronage through the use of false advertisements, contrary to K.S.A. 1988 Supp. 65-2837(b)(1).

d. That, Licensee has engaged in conduct likely to deceive the public contrary to K.S.A. 1988 Supp. 65-2836(b)(12).

e. That, Licensee has engaged in the use of false, or deceptive statements in documents connected with the practice of the Healing Arts contrary to K.S.A. 1988 Supp. 65-2837(b)(17).

IT IS THEREFORE ORDERED by the Board as follows:

1. That, the findings hereinabove made be and the same are made the order of the Board.

2. That, the Licensee, Frank J. Kutilek, M.D. is hereby publicly censured.

3. That, Licensee is entitled to an administrative review of this Order of Public Censure if a written request is received in the Board office within 15 days of the date of service of this Order upon Licensee.

IT IS SO ORDERED.

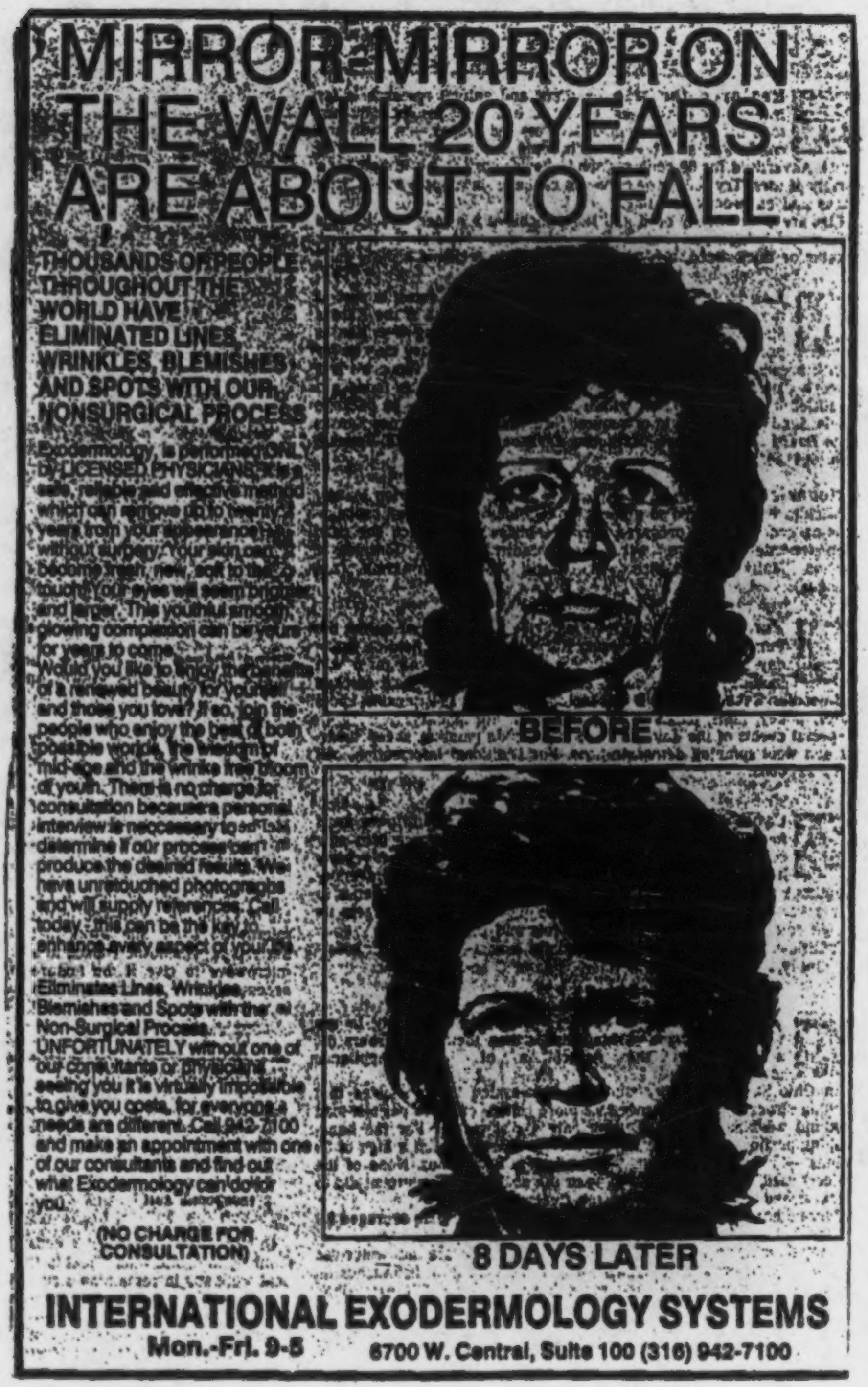
KANSAS STATE BOARD OF HEALING ARTS

RICHARD G. GANNON, Executive Director

2-23-89

Date

Prepared by:
Joseph M. Furjanic, Disciplinary Counsel
Kansas State Board of Healing Arts
900 S.W. Jackson, Suite 553
Topeka, Kansas 66612
(913) 296-7413



MIRROR MIRROR ON THE WALL 20 YEARS ARE ABOUT TO FALL

THOUSANDS OF PEOPLE THROUGHOUT THE WORLD HAVE ELIMINATED LINES, WRINKLES, BLEMISHES AND SPOTS WITH OUR NONSURGICAL PROCESS

Exodermology is performed ONLY by LICENSED PHYSICIANS. It is a safe, reliable and effective method which can remove up to twenty years from your appearance without surgery. Your skin can become fresh, new, soft to the touch. Your eyes will seem brighter and larger. This youthful smooth glowing complexion can be yours for years to come.

Would you like to enjoy the benefits of a renewed beauty for yourself and those you love? If so, join the people who enjoy the best of both possible worlds, the wisdom of mid-age and the wrinkle free bloom of youth. There is no charge for consultation because a personal interview is neccessary to determine if our process can produce the desired results. We have unretouched photographs and will supply references. Call today - this can be the key to enhance every aspect of your life.

Eliminates Lines, Wrinkles, Blemishes and Spots with the Non-Surgical Process.

UNFORTUNATELY without one of our consultants or physicians seeing you it's virtually impossible to give you costs, for everyone's needs are different. Call 942-7100 and make an appointment with one of our consultants and find out what Exodermology can do for you.

(NO CHARGE FOR CONSULTATION)

INTERNATIONAL EXODERMOLOGY SYSTEMS

Mon.-Fri. 9-5 6700 W. Central, Suite 100 (316) 942-7100

INTERNATIONAL EXODERMOLOGY SYSTEMS

DEAR DOCTOR,

Did you ever want to be a Miracle Worker?

You can work miracles with Exodermology. After more than 7,000 treatments and 23 years of research, Exodermology is the latest, most advanced form of chemexfoliation, achieving more remarkable results than the procedures now commonly used. The photos tell the story. And here's what else EXODERMOLOGY has to offer YOU:

- *UPBEAT HEALTH CARE*: You make people look younger and better - and they love you for it!

- *ELECTIVE HEALTH CARE*: No more runny noses or hopeless cases. No more nickle and dime care that drains you of time and energy. No more lengthy forms and red tape. Your patients are healthy. They come to you because they want to, and they pay their own way.

- *GREAT MONEY*: 2 patients a week (and you should average more) can bring you NET PROFITS of more than $200,000.00 per year. That's after all expenses, including marketing! The recommended price is $3500 per treatment.

- *GREAT HOURS*: Exodermology requires only about 45 minutes per patient for the actual treatment, and 10 minutes per day for typical follow-up care.

In fact, Exodermology takes so little time that you can add HUNDREDS OF THOUSANDS OF DOLLARS to your bottom line without giving up any part of your present practice - until or unless you want to.

INTERNATIONAL EXODERMOLOGY SYSTEMS TRAINING COURSE INCLUDES:

- VHS TRAINING CASSETTE - A complete step-by-step, day-by-day instructions with latest techniques of how to perform the treatment.

- THE PROVEN CHEMICAL FORMULA - Including how to prepare and where to purchase ingredients.

- PHYSICIAN'S TRAINING MANUAL providing:
  - Guidelines in making patient selections
  - Necessary medical supplies
  - Pre-op and post-op instructions
  - Techniques and application of the treatment
  - Possible complications and how to handle them.

- SCIENCE OF EXODERMOLOGY - 23 year study establishing the benefits of the treatment.

- UNDERSTANDING EXODERMOLOGY - In-depth scientific explanation of the aging skin and the effects of Exodermology.

5700 W. CENTRAL, SUITE 100, WICHITA, KANSAS 67212 • (316) 942-7100

PRO - FORMA

Note: The following Pro-Forma is based on your performing EXODERMOLOGY in your existing practice.. Fixed current expenses.. rent.. phones.. payroll.. are NOT figured in the following.........

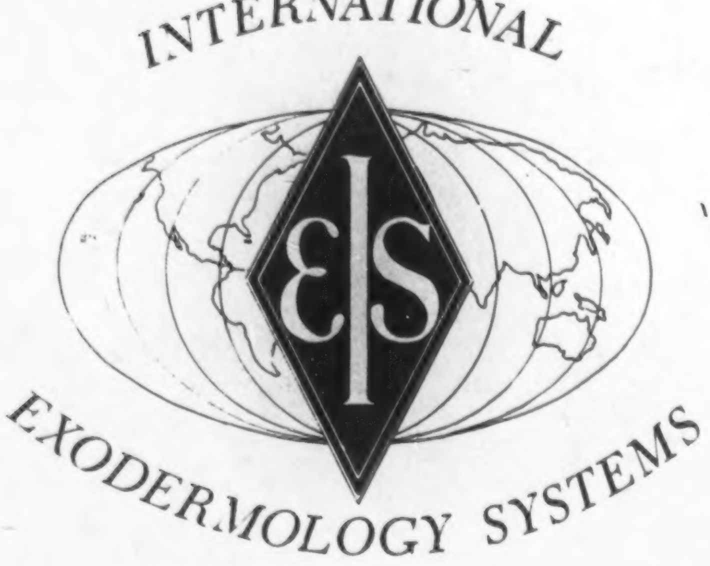
CASH FLOW PROJECTIONS

FOR EXODERMOLOGY TREATMENTS

INCOME[1]	$10,500	$17,500	$24,500	$31,500	$35,000	$35,000
Number of Treatments	(3)	(5)	(7)	(9)	(10)	(10)
Monthly Income	$10,500	$17,500	$24,500	$31,500	$35,000	$35,000
EXPENSES						
Recuperation Facility[2]	$1,440	$2,400	$3,360	$4,320	$4,800	$4,800
Medical Supplies[3]	450	750	1,050	1,330	1,500	1,500
Advertising:Newspaper	2,500	2,500	2,500	2,500	2,500	2,500
Printing/Postage	500	500	500	500	500	500
Miscellaneous	1,000	1,000	1,000	1,000	1,000	1,000
Expense Total	$5,890	$7,150	$8,410	$9,650	$10,300	$10,300
NET PROFITS	$4,610	$10,350	$16,090	$21,850	$24,700	$24,700

Total Net Profit for First Six Month Period:	$ 102,360.00
First Year Proposed Net Profit:	$ 250,560.00

[1] Gross dollar volume @ $3,500 per treatment.
[2] Based on $480 for eight day stay by each patient. (Based on a nursing home cost of $60 per day. Cost may vary depending on area.)
[3] Based on $150 per patient.


INTERNATIONAL
EIS
EXODERMOLOGY SYSTEMS

INTERNATIONAL
EXODERMOLOGY SYSTEMS

[redacted]

Dear Dr. ,

We are sending you additional information on International Exodermology Systems. Along with the brochure and synopsis of the IES training course please find enclosed a short video describing the Exodermology treatment. While we, obviously, do not go through the entire treatment process we do show some of the highlights.

After viewing this video and information, should you have any further questions please contact us. We can furnish references of physicians who have completed the IES training course for you to talk to personally. Many physicians choose to fly into Wichita to visit with the IES staff and training physicians prior to choosing their training date. We welcome your visit and will assist you in making your reservations and accomodations.

When you have finished reviewing the video we would appreciate your returing it to our home office here in Wichita. We are looking forward to having you on board with us as a member of the International Exoderlology Systems faternity.

Sincerely yours,

Joseph D. Brown
Doctor's Training Represenative

JB/ks

YOUR INTERNATIONAL EXODERMOLOGY TRAINING COURSE INCLUDES:

EIGHT DAYS OF HANDS-ON TRAINING - Conferences and seminars with IES physicians and staff.

TWO COMPLETE FACIAL TREATMENTS - for patients from your own area. (A physician may pay for his course by selling two or three treatments in his area and bring these patients with him for his training.)

VHS TRAINING CASSETTE - A complete step-by-step, day-by-day instruction with the latest techniques of how to perform the treatment.

PHYSICIANS TRAINING MANUAL - Providing:
Guidelines in making patient selections
Necessary medical supplies
Pre-op and Post-op instructions
Techniques and application of the treatment
Possible complications and how to handle them

SCIENCE OF EXODERMOLOGY - 23 year study establishing the benefits of the treatment.

UNDERSTANDING EXODERMOLOGY - In-depth scientific explanation of the aging skin and the effects of Exodermology.

MARKETING PROGRAM - Including:
Methods of advertising _ complete with 6 different ad layouts
Receptionist training manual - teaching your receptionist how to handle inquiries and booking maximum number of consulations.
Consultant training maunal - a step-by-step guide on how to handle a consultation, questions asked, overcome objections and arranging details of the treatment
Forms and Records - All necessary forms and records you will require so that you may begin immediately
Brochure Layout - "Camera ready copy" for printing of a patient information brochure to send to present and prospective patients
Before and After Photograph Album - Unretouched photos excitingly demonstrate the miraculous results of Exodermology. (This marketing tool alone would require tens of thousands of dollars to put together.)

IN OTHER WORDS, WE ARE PROVIDING YOU NOT ONLY WITH ACTUAL HANDS-ON TRAINING, THE LATEST PROCEDURES, TECHNIQUES AND FORMULAS, MANUALS AND VIDEO FOR FUTURE REFERENCE, BUT PROVEN MARKETING TOOLS THAT CAN PROVIDE YOU WITH A REWARDING ADDITIONAL INCOME.

AND IT'S TAX DEDUCTIBLE

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6700 W. CENTRAL, SUITE 100, WICHITA, KANSAS 67212 • (316) 942-7100

MARKETING PROGRAM Including:

1. Methods of advertising - complete with 6 different proven ad layouts.

2. Receptionists Training Manual - teaching your receptionists how to handle inquiries and booking maximum number of consultations.

3. Consultants Training Manual - step-by-step guide on how to handle a consultation, handle questions asked, overcome objections and arranging details of treatment.

4. Methods of acquiring new patients.

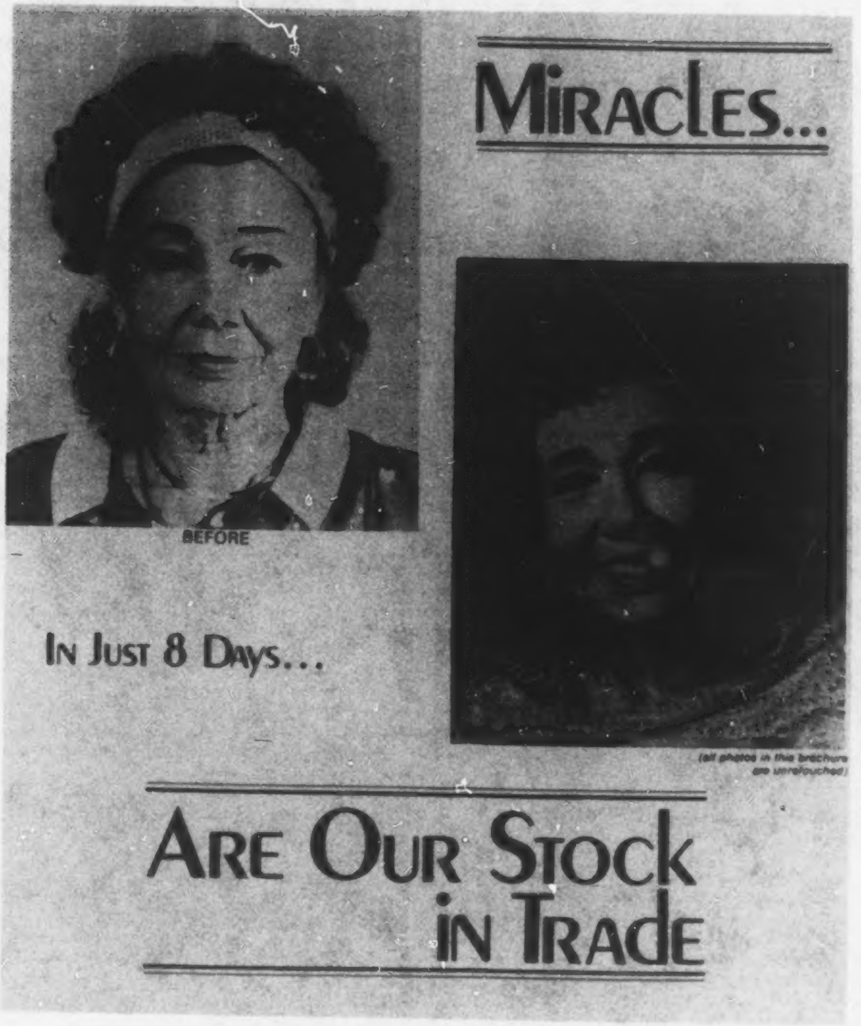
5. Forms and records - All necessary forms and records you will require so that you can begin immediately.

6. Brochure Layout - "Camera-ready copy" for the printing of a patient information brochure to send to present and prospective patients.

7. Before and after photograph album - unretouched photos excitingly demonstrate the miraculous results of EXODERMOLOGY. (This marketing tool alone would require years and tens of thousands of dollars to put together if one were to start from scracth.

8. ALSO AVAILABLE: Membership in Exodermology Society. COMPLETE WITH Board Certification, Physicians "Hot Line", Hands-on training, Yearly Seminars, Quarterly Up-date Newsletter.

IN OTHER WORDS, WE ARE PROVIDING YOU WITH NOT ONLY THE LATEST PROCEDURES, TECHNIQUES AND FORMULAS, BUT PROVEN MARKETING TOOLS THAT CAN PROVIDE YOU WITH $200,000 TO $400,000 PER YEAR ADDITIONAL INCOME.



MIRACLES...

BEFORE

IN JUST 8 DAYS...

(all photos in this brochure are unretouched)

ARE OUR STOCK
IN TRADE

BEFORE AFTER

BEFORE AFTER

BEFORE

AFTER

BEFORE

AFTER

QUESTIONS AND ANSWERS ABOUT EXODERMOLOGY

WHAT IS EXODERMOLOGY?
Exodermology is a recognized medical procedure. The effect is similar to a face-lift, but no surgery is required.

WHAT CAN EXODERMOLOGY DO?
Just look at these unretouched photos! In person and on video-tape, the results are even more astonishing! We invite you to see for yourself.

HOW DOES EXODERMOLOGY WORK?
Aging tends to break down the polymeric bonding that gives young skin its fresh smooth appearance. As skin area begins to exceed face area, bags, folds, and wrinkles increase. Exodermology chemically dissolves the outer four layers of the skin (epidermis), and removes them as a liquid plasma. The underlying skin (dermis) shrinks, much like a sweater which has been washed. The outer layers of skin then form again over the new, wrinkle-free template of dermis. Most freckles and blemishes are eliminated by this process.

HOW LONG DOES A TREATMENT TAKE?
About a week.

IS EXODERMOLOGY PAINFUL?
There can be some discomfort during the first 4 to 6 hours similar to that of sunburn. An analgesic is usually given to relieve any such discomfort.

HOW LONG DOES A TREATMENT USUALLY LAST?
Forever. After Exodermology, the face continues to age at its normal rate. So if you look 20 years younger than your actual age when you are 50, for instance, you will still look twenty years younger when you are 70.

DOES EXODERMOLOGY WORK AS WELL AS A FACE-LIFT?
Often Much better! Exodermology achieves the same tightening and lifting effects — but unlike a surgical face-lift, Exodermology can remove wrinkles, blemishes, freckles, and acne scars; promote a fresh-looking regenerated complexion; remove flute lines around the mouth and frown lines in the T-zone of the face — all without surgical scarring, and usually at a lower cost! Just look again at these unretouched photos.

INTERNATIONAL EXODERMOLOGY SYSTEMS
6700 W. Central, Suite 100
Wichita, Kansas 67212
(316) 942-7100 1 (800) 468-4003

INTERNATIONAL EXODERMOLOGY SYSTEMS

INTERNATIONAL EXODERMOLOGY SYSTEMS
6700 W. Central, Suite 100
Wichita, Kansas 67212

TREATMENT QUESTIONS AND ANSWERS

The following are questions which seem to be asked more often about the treatment.

Q. What assurance do I have that this treatment will do for me what you say it will?

A. Some lines will not disappear because of the way you use the muscles in your face. The muscles on either side of a frown line, for instance, are well developed and every time you use them you break down the skin between them. The treatment will soften these lines and often they disappear. BUT, they will come back because these muscles will again break the skin down in a hurry if you continue to use your face in the same way you have in the past. However, you will see a vast improvement providing you cooperate during the treatment. This means that you will keep the muscles of your face as quiet as possible during the treatment. This means you will talk little and through your teeth. You will eat the same way. The one thing you must avoid is laughing during the treatment.

Q. What can this do for a teenager with acne skin?

A. If the acne is arrested the doctor can treat the problem area. If the area is deeply scarred it may have to be done more than once. However, the treatment does not work

Q. Should I have these heavy hairs removed from my face by electrolysis before my treatment?

A. Yes, if you desire. Before is better than after as your pores tighten after the treatment.

Q. I have very sensitive skin, would this make a difference in my reaction to the treatment?

A. Not likely. For example, thin skinned people usually have better results.

Q. I have several allergies; would these cause any trouble?

A. No, not usually, if the doctor knows in advance what they are.

Q. Can I use glasses while taking the treatment?

A. Yes, but you must hold them out from your nose with a little cotton so they do not touch your face.

Q. May I have visitors?

A. I discourage visitors for several reasons. Mainly, you are more likely to forget and talk and laugh which will harm your mask. Secondly, because no one looks very well and there are usually two people to a room, it is often too hard on your roommate to have strange guests in the room.

Q. Will my insurance cover any or all of this treatment?

A. Generally not, because it is considered cosmetic. Check with your insurance agent. However, it is tax deductible.

from the inside out, so the acne must be stopped. If it is still active a strong dose of straight Vitamin A for a period of about 2 - 3 months and no longer, is often suggested, but check with your personal physician.

Q. Will this treatment work on heavily pocked areas?

A. Yes. But here again, it may have to be done more than once, depending upon the depth of the pocks.

Q. Will the treatment remove scars?

A. No. Most scars go down into the dermis and the treatment only works on the epidermis. However, they often smooth over so that they seem to disappear.

Q. Are there any after effects?

A. You may have a flushed effect that might last for only a few days or might last for several weeks. Each person goes back to normal differently. Your make-up camouflages the problem areas during this time.

Q. Am I in bed during this time?

A. No. After the first two days you can do anything physical from the neck down, providing you do not pull the facial muscles. No yoga or exercises during this treatment.

Q. Is it painful?

A. Some say "yes" for a short period of time and others say "no." Most people, however, don't remember due to the sedation that is used.

Q. Is there any special care I need to have after the treatment?

A. Aftercare is minimum, however your doctor will provide complete instructions prior to leaving his facilities.

Q. Can I go out in the sun?

A. Yes, after the flush has faded completely . . . in about 2 to 3 months, depending on the individual. Of course, one reason women's skin falls apart quickly is exposure to the sun. A wise woman sunbathes her body and keeps her face shaded.

Q. How often may I have this treatment done?

A. As often as you desire. Usually, however, only once for the whole face. If with the passing of time, you seem to have a problem area, that area can be retouched.

Q. I am a little overweight and want to lose. Should I lose weight before this treatment?

A. (If you have a fat face): Yes. (If the weight is on the body only): Not necessarily, plus, you will lose about five pounds during the treatment, due to the change in your diet.

Q. Would this treatment help me get rid of facial hair?

A. No. It doesn't affect hair one way or the other.

INTERNATIONAL
EXODERMOLOGY SYSTEMS

SCIENCE
OF
EXODERMOLOGY

EXODERMOLOGY

HISTORY

In 1964. I had just completed extensive research and development of a new skin care line under the name of "Ever-Young Way" when, in my frustration to find something that really does remove wrinkles, my secretary brought me an advertisement of an eleven day non-surgical treatment that supposedly did just that, remove wrinkles. Normally I would not have thought too much about it, but in the ad there were very dramatic before and after pictures, so I decided to check it out. The address in the ad, unfortunately, was in Toronto, Canada, and at this time in my life I was living in Santa Barbara, California, a long way from Toronto, but my curiosity got the better of me and I made the necessary arrangements to go.

Upon arriving at the "Lise Emond Clinic" in Toronto, to my pleasant surprise, the clinic was filled with people in every stage of the treatment including three women preparing to leave for home with their new faces. They were all anxious to show me their before pictures. The deference was startling, they all looked at least fifteen years younger. Any skepticism I may have had before I arrived quickly turned to excitement. Even though I didn t know the details of the procedure yet, I knew I had finally found something that really worked. Then came the bad news, Mdme. Lise Emond wanted one million dollars for her formula. Obviously, she had delusions of grandeur, at least as far as I was concerned. Even though her formula was priced out of the ball game, I knew there had to be others out there somewhere.

During the next two years I searched out every person that performed any treatment that was similar to what I had seen in Toronto. That wasn't easy, for in those days the treatment was mainly done by lay people performed in some back room reminiscent of the way abortions used to be done. I did manage to find a few physicians experimenting with the treatment but they were not getting the same results as the lay people were. (The doctors also learned this precedure from lay technicians and even to this day it is not taught in med school). Persistence however won out. Although most of the people that did this type of treatment guarded their formula jealously, I was finally able to purchase one from a woman in North Africa, along with the techniques and procedures to perform it. I did, however, find that the formulas and techniques used were not problem free. Most of the formulas used were Phenol based, with anywhere from five to seven buffers added for the purpose of attempting to control the depth of cutaneous penetration, but what worked on one did not always work on another. In addition, their method of applying the solution was rather slipshod and the results were not even, resulting in a blotchy look. Most of them also just applied the solution, putting nothing over it, allowing it to then scab and peel off.(thus, the name "face peel"). And when you peel the scab off, it would have a tendency to peel deeper in one area then another. Hence, when the results were good they were very very good, but when they were bad they were terrible. This "treatment roulette wheel" did not particularly appeal to me. So I began experimenting with different formulas and techniques. (On my own body I might add.) Finally, I developed a formula that was consistent every time I used it. In stead of peeling the skin off, my new formula liquified the outer skin, always going to the basal layer of the epidermis but never beyond it, no matter how I applied it. A formula that was based on the structure of skin, not on the ability of the technician. And because it always went to the same level of the epidermis, I didn't have to worry about the solution causing scarring or blotchiness, that is as long as I was conscientious in it's application making sure that all areas were covered. In addition, I developed a new type of mask after the solution was applied that accomplished two things. First, it prevented the liquified tissue from forming a scab, (the dead, liquified tissue is a breeding ground for bacteria and is best to be removed as soon as possible), and second, with the dead tissue removed, it allows the skin to heal faster. Walla --- the birth of "Exodermology".

Now, over the past twenty-three years I have performed over seven thousand successful treatments and have trained over one hundred doctors worldwide. Not only has it provided me with a career that gives people a renewed happy outlook on life, but it has supported my continual research for other methods of conquering degenerative disease.

CLINICAL RESULTS

Although the long-lasting benefit of Exodermology has been recognized for many years, it is only recently that dermatologists discovered the scientific basis for these beneficial changes. A renowned French dermatologist, P.F. Founier (1977) made the astute but vague observation that "the long lasting results obtained seem to be due to the formation of new structures in the basal layer of the epidermis and superficial layer of the dermis". The major question, however, still remained as to what exactly were these changes.

It was not until very recently that these microscopic changes in the skin have been thoroughly investigated by medical scientists. The revelation as to what was taking place in the skin resulting from this type of treatment was the basis of the scientific investigations of a group of dermatologists at the Department of dermatology, University of Pennsylvania School of Medicine and the Department of Plastic Surgery of the University of Miami School of Medicine. The following is an account of their findings.

SKIN STRUCTURE

The skin, which covers the body, consists of two main layers, the outer layer, or the epidermis, and the underlying connective tissue layer, the dermis (figure 1.). Beneath the dermis is a looser connective tissue known as the fascia, or hypodermis. Between the epidermis and the dermis is the elastotic zone, made up of a thin band of collagen, the main supportive protein of skin, and also containing elastin. These are the basic structural elements of the skin.

Superficial skin texture and color is based on the condition of the epidermis, or outer layer. The elasticity and suppleness of the skin are based on the condition of the elastotic zone. These are both regenerated from the outer surface of the underlying dermis, which is also the area of deeper skin coloration: a healthy dermis provides a flushed, healthful look to the facial skin. Tissue damage to the dermis impairs its regenerative function and results in chronic deterioration of the epidermis and elastotic zone.

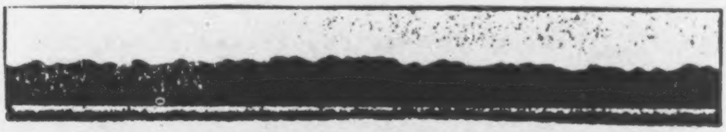
AGED AND SUN DAMAGED SKIN

A major factor in the aging of skin is excessive exposure to sunshine. This is medically known as actinic damage, or by a more recent term, heliodermatitis.

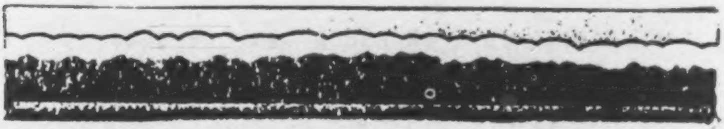
Medical examination of the skin of older persons who have been exposed to excessive sunshine reveals severe degeneration of the dermis. The elastic fibers are found to be thickened, dense, tangled and curled, and collapsed into amorphous masses. There may be numerous " spider veins" (which look like small varicose veins on the face). There may be patchy accumulations of white blood cells in the outer skin. The collagen may be greatly reduced in the elastotic zone between the dermis and the epidermis. Just beneath the epidermis there may be a band of collagen that does not contain elastin. The dermal-epidermal junction is usually flat. The epidermal cells are in disarray, with unusual variability in size and a loss of orderly differentiation. The pigment cells (melanocytes) are usually increased in number, enlarged, unevenly distributed, and often clustered. The amount of pigment in the skin cells may be strikingly variable with some cells engorged while nearby ones scarcely contain any pigment. Liver spots may be present. the basement membrane may be uneven, thickened, fuzzy, and thinned in places. Most patients will exhibit freckle-like deeply pigmented spots with well defined borders, which are called solar letigo, also known as senile letigo. They may consist of branching epidermal downgrowths, the tips of which may contain dense quantities of dark pigment, produced by clusters of enlarged pigment cells (melanocytes). This is the typical picture of aging, sun damaged skin.

HOW THE PROCESS WORKS

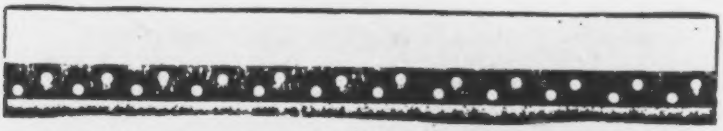
To understand how the process works, it's important that you know something about the make-up of your skin.



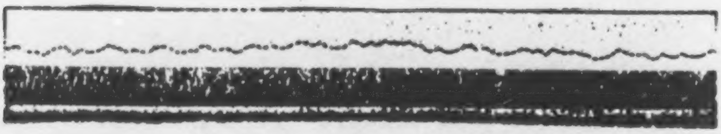
Your outer skin is made up of several layers, called epidermis. It's this outer surface that becomes rough and wrinkled due to the natural aging process and years of exposure to sun, wind and environmental pollutants.



Exodermology's regenerative process works on your outer skin. First, a specially formulated solution is applied to your face, neck, or hands. Next, a surgical paper tape mask is applied over the solution. This is removed and a powder mask applied.



During the next week, while the mask remains in place, the special solution works to diminish or remove folds around the eyes, wrinkles on the cheeks, forehead and neck, and spots associated with aging. When the mask is removed eight days later, your eyes will seem to regain their youthful size and appear wider, clear and brighter. The texture of your outer skin will be smooth, soft and firm.



Dormant cells deep in your skin also are stimulated during this remarkable process. They become renewed and bring a new radiance to your skin's outer surface. Your face will look fresh, glowing and healthy -- because your skin is actually new.

This unique, regenerative process has deep, long-lasting effects. After the treatment, your skin will have tightened and lifted, removing folds and creases. Age spots and wrinkles will have diminished or disappeared. Your skin will then begin the aging process again but it will be aging from that point forward, with the blemishes of the past gone.

SKIN CHANGES RESULTING FROM EXODERMOLOGY

Dermis

The dermal changes are usually profound and conspicuously different from untreated aging skin. A new wide band of dermis 2 to 3mm in depth forms under the epidermis. This newly formed band consists of thin, compact, parallel collagen bundles arranged horizontally to the surface. The bundles tend to be rather straight in contrast to the usual waviness. The investigations of Kligman, et al, (1985) demonstrated that these fine elastic fibers were surprisingly numerous and coursed through this band in a random arrangement. Sometimes they formed a parallel pattern conforming to the configuration of the collagen bundles. Moreover, even after 20 years, the fibers were still very fine and numerous. The ground substance was considerably less than in unpeeled skin. It was noteworthy that the small vessels within the reconstruction zone appeared to be normal, and all remaining abnormal vessels were confined to the deeper dermis which was not removed by the treatment.

In contrast to the abnormal cell clusters and discolorations around the blood vessels in untreated facial skin, the treated faces many years later rarely showed such effects around the newly formed vessels.

EPIDERMIS

The epidermis was found to be altered toward a more normal pattern, revealing a structurally sound basal layer of columnar cells and a return of the normal polarity characteristic of younger skin. The cells were found to have a more orderly arrangement than in untreated skin. Liver spots were absent. There was no evidence of microscopic horny growths. The basement membrane was more uniform in thickness and staining quality. The pigment bearing cells (melanocytes) were more regularly distributed, But some were enlarged. The epidermis contained many fine, evenly dispersed pigment (melanin) granules and the amount of pigment in adjacent cells was small and fairly uniform.

OTHER LONG-TERM EFFECTS

In my personal experience, an Exodermology treatment has always had the adventitious effect of clearing up both psoriasis (a skin disease characterized by inflammation and white, scaly patches) and vitiligo (A skin disorder characterized by pronounced mottling, seen as whitish spots with dark borders), and I have never seen these problems recur following an Exodermology treatment. No systematic study of these apparent benefits has ever been attempted, and as a consequence, neither Exodermology in particular nor chemexfoliation in general is ever prescribed as a specific remedy for psoriasis or vitiligo. My own clinical experience suggests that this might well be a productive avenue for future medical research.

There is no evidence that patients who have had Exodermology have ever developed skin cancer on the treated areas, which suggest that Exodermology may be a useful preventive therapy as well as an effective cosmetic anti-aging treatment. Skin cancers most commonly occur in sun-damaged skin, and originate in abnormal cell clusters. Since Exodermology repairs sun damage, and removes abnormal cell clusters in the outer layers of the skin, the possibility of preventive applications may also become a productive avenue for future research on Exodermology. Present clinical applications of Exodermology are restricted entirely to the field of cosmetic enhancement, however, and the treatment is not recommended for any other purpose at the present.

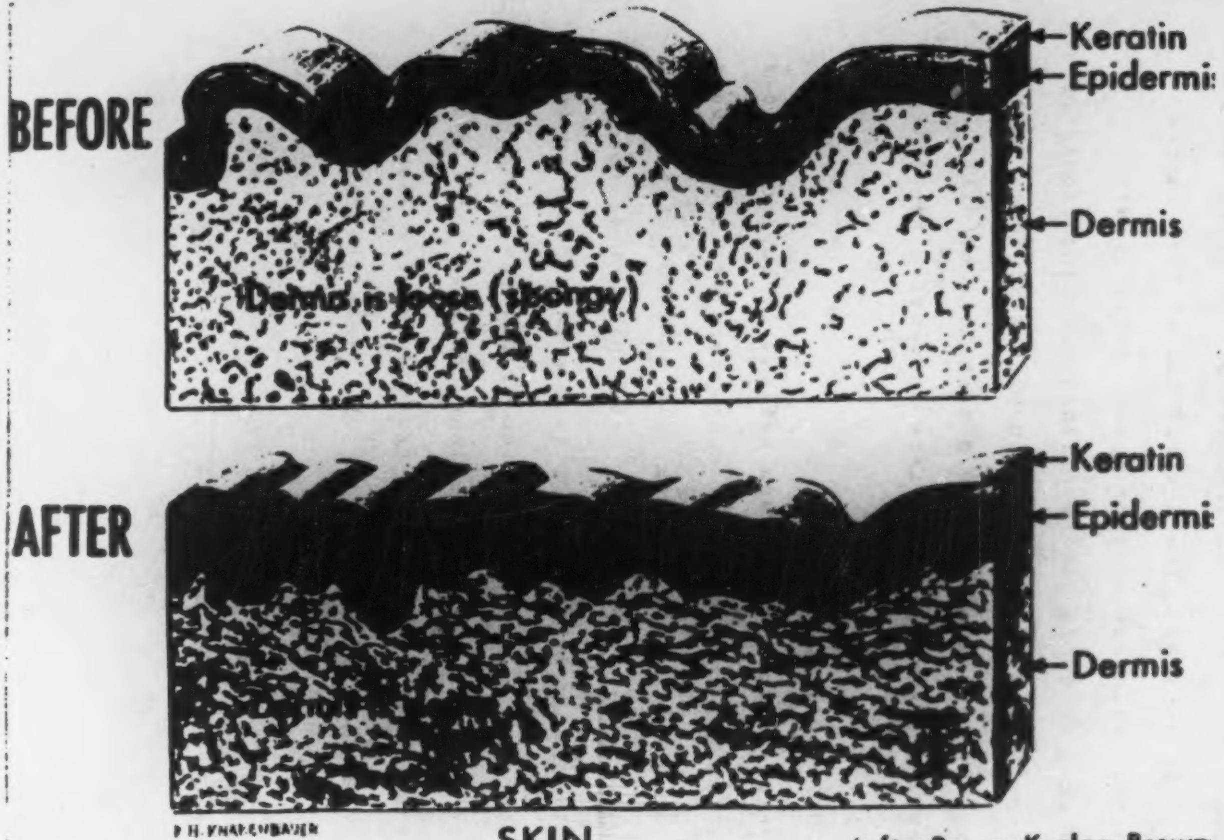
SUMMARY DISCUSSION

Over the decades the procedure has been gradually improved and expanded to include the removal of facial wrinkles, freckles and sun-damaged skin in order to improve the appearance of the aging face. The use of phenolic "face peels" has been advanced still further in the process of Exodermology, which produces a liquification of the outer epidermal-dermal layer of the skin with improved results.

There is now a substantial body of scientific data based on clinical examination of treated facial tissue which shows elastotic zone is beneficially affected and there is a dermal reconstruction. A new band of connective tissue accounts for the removal of wrinkles. The study by Kligman, Baker and Gordon (1985) clearly indicate that the dermal reconstruction lasts for at least two decades. The destruction of the damaged epidermis eliminates liver spots, horny growths, wrinkles, freckles, and abolishes mottling caused by an uneven distribution of melanin pigment. There is suggestive evidence for the possibility of other curative effects and long-term preventive benefits.

CONTRAINDICATIONS

Prior to treatment, each patient is subjected to a detailed history, physical exam, complete blood count and blood chemistry profile. In addition, E.K.G. and urinalysis are recommended. If a patient is found to be significantly diabetic (insulin dependent) or to be suffering with serious cardiac or pulmonary disease, it is recommended that the patient not have the treatment. This treatment is also not recommended for Blacks, Orientals, or Latins due to possible pigmentation problems.


BEFORE
AFTER
Keratin
Epidermis
Dermis
Dermis is loose (spongy)
Keratin
Epidermis
Dermis

SKIN (after Brown, Kaplan, Brown)

State of Kansas

Office of
RICHARD G. GANNON, EXECUTIVE DIRECTOR
CHARLENE K. ABBOTT, ADMINISTRATIVE ASSISTANT
LAWRENCE T. BUENING, JR., GENERAL COUNSEL
JOSEPH M. FURJANIC, DISCIPLINARY COUNSEL

Landon State Office Building
900 S.W. JACKSON, SUITE 553
TOPEKA, KS 66612-1256
(913) 296-7413

Board of Healing Arts

June 27, 1989

Ms. Annette Cutino
Attorney
Division of Service Industry Practices
Room H-200
Federal Trade Commission
Washington, D.C. 20580

Dear Ms. Cutino:

This is in response to your letter of June 17, 1989, as well as our telephone conversation of June 27th. We are in the process of accumulating the information we have on national marketing organizations and their activities with Kansas practitioners. A detailed response and the information we have will be forthcoming in the near future. However, in the interim, on June 26th we did receive a copy of an advertisement which was run in the Wichita Eagle Beacon on Thursday, June 22, 1989. A copy of that advertisement is enclosed.

A brief investigation into this matter reveals that the National Institute of Clinical Acupuncture is actually at the same office as a chiropractic licensee of the Board. The specific concerns that this advertisement raises is whether the claims alleged can actually be substantiated. For instance, the ad uses claims which could be construed to be guarantees as follows:

"Finally a nonsurgical treatment that works"
"You'll see improvements in: grip strength, pinch strength, decreased pain and decreased range of motion."
"As opposed to other modes of treatment, we returned all patients to original work or occupations."

I am enclosing copies of KSA 1988 Supp. 65-2836 and 65-2837. These statutes set forth the grounds from which the Board may take disciplinary action against a licensee's license. If the claims made in this advertisement cannot be substantiated, then it would appear that several of the statutes may have been violated. Possible violations would include KSA 65-2836(d), taking into consideration the manner in which "advertisement" is defined in KSA

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65-2837(d). Also, KSA 65-2836(b) may have been violated by the commission of an act of unprofessional conduct as that term is defined in KSA 65-2837(b)(1)(2), (7), (8), (12), (13), (17), (18), and (27).

If possible, the Board would like to receive either an informal or advisory opinion as to whether if, the claims and allegations made in the enclosed advertisement cannot be substantiated, there would be any violation of Federal Trade Commission policies and rules and regulations, if the Board proceeded with disciplinary action against the individual licensee responsible for the placement of their advertisement. Naturally, since the Board regulates only individuals, it would not be possible to take any action against the entity, National Institute of Clinical Acupuncture. If the claims made in the advertisement cannot be substantiated, then it would appear that any action against the National Institute of Clinical Acupuncture would fall within either the jurisdiction of the Federal Trade Commission or the authorities in the State of Kansas responsible for consumer fraud.

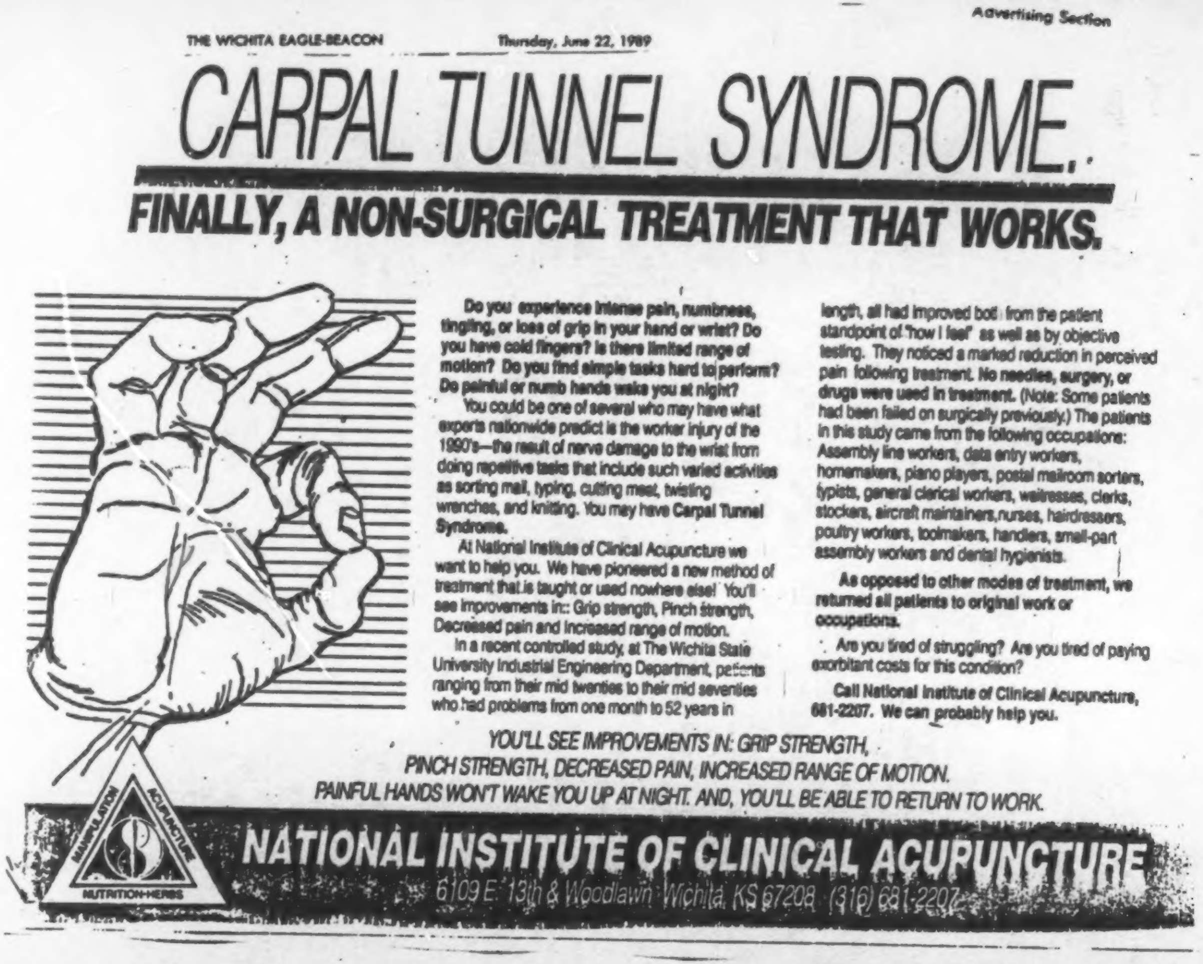
As above stated, a more detailed and complete response to your letter of June 17th will be forthcoming in the near future. However, as this ad had just been received in the Board Office, it was felt that your review and response to it would be beneficial to the Board in the immediate future.

Thank you very much for your consideration of this matter. Please feel free to contact me if you have any questions or desire any additional information.

Very truly yours,

Richard G. Gannon (State Senator, Ret.)
Executive Director

RGG/pd
Encs.



THE WICHITA EAGLE-BEACON Thursday, June 22, 1989 Advertising Section

CARPAL TUNNEL SYNDROME.

FINALLY, A NON-SURGICAL TREATMENT THAT WORKS.

Do you experience intense pain, numbness, tingling, or loss of grip in your hand or wrist? Do you have cold fingers? Is there limited range of motion? Do you find simple tasks hard to perform? Do painful or numb hands wake you at night?

You could be one of several who may have what experts nationwide predict is the worker injury of the 1990's—the result of nerve damage to the wrist from doing repetitive tasks that include such varied activities as sorting mail, typing, cutting meat, twisting wrenches, and knitting. You may have **Carpal Tunnel Syndrome.**

At National Institute of Clinical Acupuncture we want to help you. We have pioneered a new method of treatment that is taught or used nowhere else! You'll see improvements in:: Grip strength, Pinch strength, Decreased pain and increased range of motion.

In a recent controlled study, at The Wichita State University Industrial Engineering Department, patients ranging from their mid twenties to their mid seventies who had problems from one month to 52 years in length, all had improved both from the patient standpoint of "how I feel" as well as by objective testing. They noticed a marked reduction in perceived pain following treatment. **No needles, surgery, or drugs were used in treatment.** (Note: Some patients had been failed on surgically previously.) The patients in this study came from the following occupations: Assembly line workers, data entry workers, homemakers, piano players, postal mailroom sorters, typists, general clerical workers, waitresses, clerks, stockers, aircraft maintainers,nurses, hairdressers, poultry workers, toolmakers, handlers, small-part assembly workers and dental hygienists.

As opposed to other modes of treatment, we returned all patients to original work or occupations.

Are you tired of struggling? Are you tired of paying exorbitant costs for this condition?

Call National Institute of Clinical Acupuncture, 681-2207. We can probably help you.

YOU'LL SEE IMPROVEMENTS IN: GRIP STRENGTH,
PINCH STRENGTH, DECREASED PAIN, INCREASED RANGE OF MOTION.
PAINFUL HANDS WON'T WAKE YOU UP AT NIGHT. AND, YOU'LL BE ABLE TO RETURN TO WORK.

NATIONAL INSTITUTE OF CLINICAL ACUPUNCTURE
6109 E. 13th & Woodlawn Wichita, KS 67208 (316) 681-2207

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF
THE CHAIRMAN

RECEIVED
JUL 21 1989

July 17, 1989

Mr. Richard G. Gannon
Executive Director
State of Kansas Board
of Healing Arts
900 Southwest Jackson
Suite 553
Topeka, Kansas 66612-1256

Dear Mr. Gannon:

I am writing you to correct some misapprehensions that you and members of your board may have about how the Commission perceives the role of state medical boards in policing false and misleading advertising by health care providers.

In your testimony of May 31, 1989, before the Subcommittee on Regulation, Business Opportunities, and Energy of the House Committee on Small Business, U.S. House of Representatives, you indicated that "various FTC and court rulings have made it extremely difficult to discipline a doctor solely on the basis of advertising with the exception of the most blatant violations."

State medical boards should not feel constrained by the FTC from bringing disciplinary actions that are based on false, misleading, or deceptive advertising, either alone or in combination with other practices that are detrimental to the health and safety of consumers. I am enclosing a copy of my testimony before the Subcommittee, in which I address the Commission's interest in preserving the free flow of truthful and nondeceptive advertising by health care providers and stress the need for effective state action to prevent local practitioners from engaging in false and deceptive advertising. I hope that my statement will help to dispel any confusion you may have regarding the Commission's interest in this area.

You also stated that your board's General Counsel, Mr. Laurence Buening, had interpreted a recent telephone call to him from an FTC staff attorney as an inquiry to ensure that your board had not placed restraints on truthful advertising as a result of its disciplinary action against two doctors for falsely advertising a chemical face peel process known as exodermology or endodermology. You indicated in your statement that such contacts "cause consternations and may have a chilling effect if the result is to become embroiled in actions brought by the Federal Trade Commission."

I understand that, at the hearing, Mr. Kelly of the FTC staff explained to you prior to your testimony that the only purpose for contacting your board about that matter was in furtherance of our own investigation of the promotion of this process and that the contact did not involve questions regarding the propriety of the board action itself. The staff attorney who called Mr. Buening reported that he was very friendly and helpful in answering her questions and at no time asked why she was expressing an interest in the matter.

In view of your belief that the advertising that led to your board's action was provided by an out-of-state corporation and that federal assistance is needed in policing such interstate activities, I am dismayed that you and your board would consider a call from the FTC regarding the matter as chilling. In any event, I hope that my statement sets that record straight, and that, in the future, our two agencies can cooperate effectively to address false and deceptive advertising by physicians.

Sincerely,

Daniel Oliver

Daniel Oliver
Chairman

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

BUREAU OF
CONSUMER PROTECTION

RECEIVED
JUL 21 1989

July 18, 1989

Richard G. Gannon (State Senator, Ret.)
Executive Director
State of Kansas
Board of Healing Arts
Landon State Office Building
900 S.W. Jackson, Suite 553
Topeka, Kansas 66612-1256

Dear Senator Gannon:

Thank you for your letter requesting our reaction to an ad recently run by the National Institute of Clinical Acupuncture. In particular, you wanted some advice on whether, if certain claims that appeared in the ad could not be substantiated, there would be a violation of Federal Trade Commission policies and rules. This letter replies to that request.[1]

At the outset, the Commission's ad substantiation policy statement makes clear that the failure of an advertiser to have substantiation for objective claims in advertising constitutes a violation of Section 5 of the FTC Act.[2] It appears that the specific ad you are focusing on makes a number of objective and express claims for its treatment of Carpal Tunnel Syndrome. If such claims were found to be either false or unsubstantiated, a violation of the standards set out in Section 5 would, thus, have occurred. In addition to the advertised claims you have identified in your letter, the ad purports to describe the findings of a "recent controlled study" that showed improvement both from the "patient standpoint of 'how I feel' as well as by objective testing." If we were examining the claims in that ad, we would also ask the company for information on how that study was conducted and how its results support the conclusions set out in the ad.[3]

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[1] The views expressed in this letter are, unless otherwise indicated, the views of staff, and, as such, do not bind the Commission.

[2] "(A) firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair or deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act." FTC Policy Statement Regarding Advertising Substantiation, 49 Fed. Reg. 30999, 31000, August 2, 1984 (attached).

I have included for your review a recent decision by the Commission that applied the ad substantiation standards to particular health claims made in an advertisement. That opinion should help you understand how the Commission applies the ad substantiation standards to specific ads and supporting evidence.[4]

Please feel free to contact me if you have any further questions, and to keep us informed on the progress of your inquiry into the advertising practices of the Institute.

Sincerely,

Richard F. Kelly
Assistant Director

Attachments (2)

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[3] "Many ads contain express or implied statements regarding the amount of support the advertiser has for the product claim. When the substantiation is express (e.g. 'test proves', 'doctors recommend', and 'studies show'), the Commissioner expects the firm to have at least the advertised level of substantiation." Id.

[4] In re Thompson Medical Co. Inc., 104 F.T.C. 648, 786 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986).

have been convicted of crimes involving dishonesty or breach of trust. Such consent is required under section 19 of the Federal Deposit Insurance Act (12 U.S.C. 1829). The form has been assigned OMB No. 3064-0018 which currently expires on September 30, 1984. It is estimated that the annual burden on the average bank to prepare the form is 16 hours.

Dated: July 25, 1984.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 84-[illegible] Filed 8-1-84; 8:45 am]

BILLING CODE 6714-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the folowing agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, D.C. Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington D.C. 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-000150-076.

Title: Trans-Pacific Freight Conference of Japan/Korea.

Parties:

American President Lines, Ltd.
Barber Blue Sea Line
Hapag-Lloyd AG
Japan Line, Ltd.
Kawasaki Kisen Kaisha, Ltd.
Korea Marine Transport Co., Ltd.
Lykes Bros. Steamship Company, Inc.
Mitsui O.S.K. Lines, Ltd.
A.P. Moller Maersk Line
Neptune Orient Lines, Ltd.
Nippon Yusen Kaisha
Orient Overseas Container Line, Inc.
Sea-Land Service, Inc.
Showa Line, Ltd.
United States Lines, Inc.
Yamashita-Shinnihon Steamship Co. Ltd.

Synopsis: The proposed agreement would establish independent action procedures for the conference membership.

Agreement No.: 202-008103-075.

Title: Japan/Korea-Atlantic & Gulf Freight Conference.

Parties:

Barber Blue Sea Line
Japan Line, Ltd.
Kawasaki Kisen Kaisha, Ltd.
Lykes Bros. Steamship Company, Inc.
Mitsui O.S.K. Lines, Ltd.
A.P. Moller-Maersk Line
Neptune Orient lines, Ltd.
Nippon Yusen Kaisha
Orient Overseas Container Line, Inc.
United States Lines, Inc.
Yamashita-Shinnihon Steamship Co., Ltd.

Synopsis: The proposed agreement would establish independent action procedures for the conference membership.

Agreement No.: 202-005700-039.

Title: New York Freight Bureau.

Parties:

Barber Blue Sea Line
Japan Line, Ltd
A.P. Moller-Maersk Line
Mitsui O.S.K. Lines, Ltd.
Nippon Yusen Kaisha
United States Lines, Inc.
Yamashita-Shinnahon Steamship Co. Ltd.

Synopsis: The proposed agreement would establish independent action procedures for the conference membership.

Agreement No: 202-007540-042.

Title: United States Atlantic & Gulf/Southeastern Caribbean Conference.

Parties:

Concorde/Nopal Line
Puerto Rico Marine Management, Inc.
Sea-Land Service
Shipping Corporation of Trinidad and Tobago, Ltd.

Synopsis: The proposed agreement would reduce from ten calendar days to two business days the amount of time required to take independent action and reduce from two business days to one business day the amount of time a member has to respond to a telephone poll conducted by the conference staff. The parties have requested a shortened review period.

Agreement No.: 202-008190-015.

Title: Japan-Puerto Rico & Virgin Islands Freight Conference.

Parties:

Japan Line, Ltd.
Kawasaki Kisen Kaisha, Ltd.
Mitsui O.S.K. Lines, Ltd.
Nippon Yusen Kaisha
Yamashita-Shinnihon Steamship Co., Ltd.

Synopsis: The proposed agreement would establish independent action procedures for the conference membership.

Agreement No.: 212-009038-0[illegible]

Title: Companhia de Navegacao Lloyd Brasileiro—Companhia de Navegacao Maritima Netumar Association Agreement.

Parties:

Companhia de Navegacao Lloyd Brasileiro
Companhia de Navegacao Maritima Netumar

Synopsis: The proposed agreement would eliminate the existing termination date of September 30, 1984, extending the agreement indefinitely.

By Order of the Federal Maritime Commission.

Dated. July 27, 1984.

Francis C. Hurney,

Secretary.

[FR Doc. 84-[illegible] Filed 8-1-84; 8:45 am]

BILLING CODE 6730-01-M

Security for the Protection of the Public; Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Pub. L. 89-777 (80 Stat. 1357, 1358) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540): Carnival Cruise Lines, Inc. and Sunbury Assets, Inc., c/o Carnival Cruise Lines, 3015 Biscayne Boulevard, Miami, Florida 33137.

Dated: July 30, 1984.

Francis C. Hurney,

Secretary.

[FR Doc. 84-20423 Filed 8-1-84; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL TRADE COMMISSION

Policy Statement Regarding Advertising Substantiation Program

AGENCY: Federal Trade Commission.

ACTION: The Federal Trade Commission has issued a Policy Statement regarding its advertising substantiation program.

SUMMARY: The Federal Trade Commission has issued a Policy Statement that articulates its policy regarding the legal requirement pursuant to section 5 of the Federal Trade Commission Act that advertisers and ad agencies have a reasonable basis for their objective claims before their initial

dissemination. This Policy Statement is a result of a review of the comments filed in response to a public inquiry that the Commission initiated in March 1983. The Policy Statement reaffirms the Commission's commitment to the reasonable basis requirement and at the same time explains several refinements that will lead to a more efficient program of law enforcement, with lower costs to the public, the advertising industry, and the agency.

FOR FURTHER INFORMATION CONTACT: Collot Guerard, Federal Trade Commission, Bureau of Consumer Protection, Washington, D.C. 20580, 202-376-8648.

FTC Policy Statement Regarding Advertising Substantiation

Introduction

On March 11, 1983, the Commission published a notice requesting comments on its advertising substantiation program.[1] To facilitate analysis of the program, the notice posed a number of questions concerning the program's procedures, standards, benefits, and costs, and solicited suggestions for making the program more effective. Based on the public comments and the staff's review, the Commission has drawn certain conclusions about how the program is being implemented and how it might be refined to serve better the objective of maintaining a marketplace free of unfair and deceptive acts or practices. This statement articulates the Commission's policy with respect to advertising substantiation.

The Reasonable Basis Requirement

First, we reaffirm our commitment to the underlying legal requirement of advertising substantiation—that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated.

The Commission intends to continue vigorous enforcement of this existing legal requirement that advertisers substantiate express and implied claims, however conveyed, that make objective assertions about the item or service advertised. Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims. These representations of substantiation are material to consumers. That is, consumers would be less likely to rely on claims for products and services if they knew the advertiser did not have a reasonable basis for believing them to be true.[2] Therefore, a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of section 5 of the Federal Trade Commission Act.

Standards for Prior Substantiation

Many ads contain express or implied statements regarding the amount of support the advertiser has for the product claim. When the substantiation claim is express (*e.g.*, "tests prove", "doctors recommend", and "studies show"), the Commission expects the firm to have at least the advertised level of substantiation. Of course, an ad may imply more substantiation than it expressly claims or may imply to consumers that the firm has a certain type of support; in such cases, the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers.

Absent an express or implied reference to a certain level of support, and absent other evidence indicating what consumer expectations would be, the Commission assumes that consumers expect a "reasonable basis" for claims. The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable. Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses.

One issue the Commission examined was substantiation for implied claims. Although firms are unlikely to possess substantiation for implied claims they do not believe the ad makes, they should generally be aware of reasonable interpretations and will be expected to have prior substantiation for such claims. The Commission will take care to assure that it only challenges reasonable interpretations of advertising claims.[3]

Procedures for Obtaining Substantiati

In the past, the Commission has sought substantiation from firms in two different ways: Through industry-wide "rounds" that involved publicized inquiries with identical or substantially similar demands to a number of firms within a targeted industry or to firms in different industries making the same type of claim; and on a case-by-case basis, by sending specific requests to individual companies under investigation. The Commission's review indicates that "rounds" have been costly to both the recipient and to the agency and have produced little or no law enforcement benefit over a case-by-case approach.

The Commission's traditional investigatory procedures allows the staff to investigate a number of firms within an industry at the same time, to develop necessary expertise within the area of investigation, and to announce our activities publicly in circumstances where public notice or comment is desirable. The Commission intends to continue undertaking such law enforcement efforts when appropriate. However, since substantiation is principally a law enforcement tool and the Commission's concern in such investigations is with the substantiation in the *advertiser's* possession, there is little, if any, information that the public could contribute in such investigations. Therefore, the Commission anticipates that substantiation investigations will rarely be made public before they are completed.

Accordingly, the Commission has determined that in the future it will rely on nonpublic requests for substantiation directed to individual companies via an informal access letter or, if necessary, a formal civil investigative demand. The Commission believes that tailored, firm-specific requests, whether directed to one firm or to several firms within the same industry, are a more efficient law enforcement technique. The Commission cannot presently foresee circumstances under which the past approach of industry-wide rounds would be appropriate in the ad substantiation area.

Relevance of Post-Claim Evidence in Substantiation Cases

The reasonable basis doctrine requires that firms have substantiation before disseminating a claim. The Commission has on occasion exercised its discretion, however, to consider supporting materials developed after dissemination.[8] The Commission has not previously identified in one document the circumstances in which it may, in its discretion, consider post-claim evidence in substantiation cases.[9] Such guidance can serve to clarify the program's actual operation as well as focus consideration of post-claim evidence on cases in which it is appropriate.

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[1] 48 FR 10471, March 11, 1983.

[2] Nor presumably would an advertiser have made such claims unless the advertiser thought they would be material to consumers.

[3] Individual Commissioners have expressed differing views as to how claims should be interpreted so that advertisers are not held to outlandish or tenuous interpretations. Notwithstanding these variations in approach, the focus of all Commissioners on reasonable interpretations of claims is intended to ensure that advertisers are not required to substantiate claims that were not made.

The Commission emphasizes that as a matter of law, firms lacking a reasonable basis before an ad is disseminated violate section 5 of the FTC Act and are subject to prosecution. The goal of the advertising substantiation requirement is to assure that advertising is truthful, however, and the truth of falsity of a claim is always relevant to the Commission's deliberations. Therefore, it is important that the agency retain the discretion and flexibility to consider additional substantiating evidence, not as a substitute for an advertiser's prior substantiation, but rather in the following circumstances:

- When deciding, before issuance of a complaint, whether there is a public interest in proceeding against a firm;
- When assessing the adequacy of the substantiation an advertiser possessed before a claim was made; and
- When deciding the need for or appropriate scope of an order to enter against a firm that lacked a reasonable basis prior to disseminating an advertisement.

First, using post-claim evidence to evaluate the truth of a claim, or otherwise using such evidence in deciding whether there is a public interest in continuing an investigation or issuing a complaint, is appropriate policy. This does not mean that the Commission will postpone action while firms create post-claim substantiation to prove the truthfulness of claims, nor does it mean that subsequent evidence of truthfulness absolves a firm of liability for failing to possess prior substantiation for a claim. The Commission focuses instead on whether existing evidence that claims are true should lead us in the exercise of our prosecutorial discretion to decline to initiate a law enforcement proceeding. If available post-claim evidence proves that the claim is true, issuing a complaint against a firm that may have violated the prior substantiation requirement is often inappropriate, particularly in light of competing demands on the Commission's resources.

Second, post-claim evidence may indicate that apparent deficiencies in the pre-claim substantiation materials have no practical significance. In evaluating the adequacy of prior substantiation, the Commission will consider only post-claim substantiation that sheds light on pre-existing substantiation. Thus, advertisers will not be allowed to create entirely new substantiation simply because their prior substantiation was inadequate.

Finally, the Commission may use post-claim evidence in determining the need for or appropriate scope of an order to be entered against a firm that lacked a reasonable basis. Thus, when additional evidence offered for the first time at trial suggests that the claim is true, the Commission may frame a narrower order than if there had been no post-claim evidence.

The Commission remains committed to the prior substantiation requirement and further believes that these discretionary factors will provide necessary flexibility. The Commission will consider post-claim evidence only in the circumstances listed above. But, whether it will do so in any particular case remains within its discretion.

Self-Regulation Groups and Government Agencies

The Commission traditionally has enjoyed a close working relationship with self-regulation groups and government agencies whose regulatory policies have some bearing on our law enforcement initiatives. The Commission will not necessarily defer, however, to a finding by a self-regulation group. An imprimatur from a self-regulation group will not automatically shield a firm from Commission prosecution, and an unfavorable determination will not mean the Commission will automatically take issue, or find liability if it does. Rather the Commission will make its judgment independently, evaluating each case on its merits. We intend to continue our useful relationships with self-regulation groups and to rely on the expertise and findings of other government agencies in our proceedings to the greatest extent possible.

Issued: July 27, 1984.

By direction of the Commission.

Benjamin I. Berman,
Acting Secretary.

[FR Doc. 84-20445 Filed 8-1-84; 8:45 am]

BILLING CODE 6750-01

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[8] The Commission's evidentiary rule, 16 CFR 3.40, has sometimes been interpreted as precluding introduction of post-claim substantiation. In fact, it does not. Section 3.40 only provides a sanction against the introduction of evidence that should have been produced in response to a subpoena, but was not.

[9] The distinction between pre-claim and post-claim evidence is only relevant when the charge is lack of substantiation. For other charges, such as falsity, when evidence was developed is irrelevant to its admissibility at trial.

~~DEPARTMENT OF HEALTH AND HUMAN SERVICES~~

~~Food And Drug Administration~~

~~[Docket No. 83C-0395]~~

~~Polymer Technology Corp.; Withdrawal of Color Additive Petitions~~

~~**AGENCY:** Food and Drug Administration.~~

~~**ACTION:** Notice.~~

~~**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal without prejudice of the color additive petition (CAP 3C0165) for use of D&C Green No. 6 and D&C Yellow No. 11 in contact lenses, and the withdrawal without prejudice of those portions of the color additive petition (CAP 3C0163) that requested use of D&C Green No. 6 and D&C Yellow No. 11 in contact lenses. These petitions were filed by Polymer Technology Corp.~~

~~**FOR FURTHER INFORMATION CONTACT:** Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.~~

~~**SUPPLEMENTARY INFORMATION:** In the Federal Register of January 28, 1983 (48 FR 4051), FDA announced that three color additive petitions (CAP 3C0163, 3C0164, and 3C0165) had been filed by Polymer Technology Corp., 33 Industrial Way, Wilmington, MA 01887, proposing that the color additive regulations be amended to provide for the safe use of D&C Green No. 6, D&C Yellow No. 11, and D&C Red No. 17 for coloring contact lenses. The petitions were filed under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).~~

~~In the Federal Register of March 29, 1983 (48 FR 13020), FDA issued a final rule listing D&C Green No. 6 for use as a color additive for coloring contact lenses (21 CFR 74.3206). FDA issued this regulation in response to several color additive petitions for use of D&C Green No. 6 in contact lenses, including CAP 3C0164. Thus, the agency completed final action in response to petition CAP 3C0164 with the publication of the listing regulation for D&C Green No. 6 in the Federal Register, and the request for the use of D&C Green No. 6 in CAP's 3C0163 and 3C0165 is now unnecessary.~~

III

It is further ordered, That so much of the complaint as relates t o Paragraph 12(f) be, and the same hereby is, dismissed.

Opinion of the Commission

By Douglas, *Commissioner:*

I. INTRODUCTION

Thompson Medical Company, Inc. ("Thompson") is a pharmaceutical company that sells several different over-the-counter ("OTC") drugs. One such drug is Aspercreme, a topical cream rub or lotion whose active ingredient is 10% triethanolamine salicylate ("TEA/S"). Thompson has marketed Aspercreme as a remedy for relief of minor arthritis pain since 1976, after purchasing it from the Sperti Drug Company. At first, Thompson followed Sperti's practice of marketing the product locally in Ohio. Starting in 1978, however, Thompson began a successful national advertising campaign for Aspercreme which saw sales of the product increase from $589,000 in 1978 to $5.9 million in 1981 (IDF 74.)[1] [2]

On February 5, 1981, the Commission issued a complaint against Thompson and its advertising agency, Ogilvy and Mather, Inc. The complaint charges that Thompson's marketing campaign for Aspercreme involved the following deceptive representations:

Complaint Paragraph Number	Alleged Representation
10(a), 16	Aspercreme contains aspirin.[2]
10(b)	Aspercreme is a recently discovered or developed drug product
10(c)	Valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatic conditions, and their symptoms.
12(a)	Aspercreme is an effective drug for the relief of minor arthritis and its symptoms.
12(b)	Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor arthritis and its symptoms.
12(c)	Aspercreme is a more effective drug than orally-ingested aspirin for the relief of minor arthritis and its symptoms. [3]
12(d)	Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms.
12(e)	Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder.
12(f)	The use of Aspercreme will result in no side effects.
14	Thompson had a reasonable basis for representations listed in Complaint Paragraphs 12(a)-(f) at the time they were made.

The complaint alleges that representations listed in Complaint Paragraphs 10, 14, and 16 are false, misleading, and deceptive. It further alleges that Thompson lacked a reasonable basis for the representations listed in Complaint Paragraph 12.

The case was assigned to Administrative Law Judge Montgomery K. Hyun for hearing. On July 7, 1983, Judge Hyun entered his initial decision, which found against Thompson on all charges except those relating to claims that Aspercreme had no side effects (Comp. ¶12(f)). The order he adopted requires Thompson to have a reasonable basis for claims that any OTC analgesic drug is effective for the relief of symptoms of musculoskeletal disorder, and for comparative efficacy claims made for such a [4] drug. The order further prohibits Thompson from: (1) using the brand name "Aspercreme" unless it is accompanied by a disclosure that the product does not contain aspirin; (2) representing that a product is new if it has been generally available for purchase in the United States for more than one year; and (3) misrepresenting any test or study.

Thompson appeals from the ALJ's findings as to liability. Thompson's principal arguments on appeal are: (1) the ALJ erred in finding that Thompson lacked reliable and credible information constituting a reasonable basis for the efficacy claims it made for Aspercreme; (2) the ALJ erred in finding Aspercreme not to be an effective drug for the relief of minor arthritis or rheumatism pains; and (3) the ALJ erred in finding that either the trademark "Aspercreme" or the product 's advertising deceptively represent that the product contains aspirin. Complaint counsel appeal from the ALJ's decision not to prohibit Thompson from using the "Aspercreme" brand name. Complaint counsel also appeal the ALJ's decision to limit Part I of the order to OTC analgesic drugs, rather than all OTC drugs, and not to have Part I prohibit false ingredient representations involving any brand name and any active ingredient.

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[1] The following abbreviations are used in this opinion:

ID - initial decision page number
IDF - initial decision finding number
Tr - transcript of testimony page number
CX - complaint counsel's exhibit number
CPF - complaint counsel's proposed findings of fact and conclusions of law finding number
CMF - complaint counsel's memorandum supporting proposed findings of fact and conclusions of law page number
CAP - complaint counsel's appeal brief page number
CAB - complaint counsel's answering brief page number
RX - respondent's exhibit number
RPF - respondent's proposed finding of fact and conclusions of law finding number
RMF - respondent's memorandum supporting proposed findings of fact and conclusions of law page number
RAP - respondent's appeal brief page number
RRB - respondent's reply brief page number

[2] Complaint Paragraph 10(a) charges Thompson generally with representing that Aspercreme contains aspirin. Complaint Paragraph 16 specifically charges that use of the trademark "Aspercreme" constitutes such a representation.

[3] Prior to Judge Hyun's decision, the Commission adopted a Decision and Order settling the charges against Ogilvy & Mather. *In the Matter of Ogilvy & Mather International, Inc.,* Docket No. [illegible] Decision and Order [illegible] January 4, 1984 (103 F.T.C. 1 (1984)).

We generally agree with the ALJ's findings and conclusion and, except as noted in this opinion, adopt them as our own. Our analysis of the issues presented here is in four parts. First, we determine whether or not Thompson made the representations alleged in the complaint. Second, we evaluate whether or not the representations were material. Third, we examine whether or not [5] the claims were likely to mislead consumers acting reasonably under the circumstances.[4] Finally, in light of our determinations as to the extent and severity of Thompson's deceptive advertising, we consider the appropriate scope of an order prohibiting such conduct in the future.

II. DID THOMPSON MAKE THE REPRESENTATIONS ALLEGED IN THE COMPLAINT?

1. *Legal Framework*

In this part of the opinion, we examine whether Thompson's advertising expressly or impliedly conveyed to consumers the representations listed in the complaint. As our discussion below will show, we conclude that it generally did. Before analyzing the advertising itself, however, we will set out the standards by which we do so. [6]

As we noted in *Cliffdale Associates*,[5] we will deem an advertisement to convey a claim if consumers acting reasonably under the circumstances would interpret the advertisement to contain that message. The purpose of such a requirement is to ensure that the flow of useful, accurate information to consumers will not be deterred by advertisers' fears that they could be held responsible for claims that they could not reasonably have known consumers were going to receive from the ads in question.

In evaluating what message an ad could reasonably be interpreted as containing, the Commission has traditionally distinguished between express and implied claims. Express claims are ones that directly state the representation at issue. Because the message is stated unequivocally, it is reasonable to interpret the ads as intending to make the claim.[6] Implied claims are any claims that are not express. They range from claims that would be virtually synonymous with an express claim [7] through language that literally says one thing but strongly suggests another to language which relatively few consumers would interpret as making a particular representation.[7]

Because of this wide range, the Commission employs two different techniques in evaluating whether an advertisement contains implied claims. One is to look at evidence from the advertisement itself. We often conclude that an advertisement contains an implied claim by evaluating the contents of the advertisement and the circumstances surrounding it. This technique is primarily useful in evaluating advertisements whose language or depictions are clear enough, though not express, for us to conclude with confidence after examining the interaction of all the different elements in them that they contain a particular implied claim.

If our initial review of evidence from the advertisement itself does not allow us to conclude with confidence that it is reasonable to read an advertisement as containing a particular implied message, we will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a [8] reading of the ad is reasonable.[8] For example, in this case the conflicting messages in some elements of Aspercreme's ads caused us to examine extrinsic evidence to determine what net impression(s) the entire ad could reasonably be interpreted as giving to consumers.[9]

The extrinsic evidence we prefer to use and to which we give great weight is direct evidence of what consumers actually thought upon reading the advertisement in question. Such evidence will be in the form of consumer survey research for widely distributed ads, such as those involved in this proceeding. Ads of that sort are directed at so large an audience that it is too costly to obtain the statements of enough individual consumers in another manner (*e.g.*, by way of affidavits) to be reasonably confident that the consumers' views on the record of the proceeding were representative of the entire [9] group to which the ad was addressed. Where we use surveys in lieu of individual testimony, the surveys are methodologically sound; they draw valid samples from the appropriate population, ask appropriate questions in ways that minimize bias, and analyze results correctly.[10]

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[4] As Commissioner Bailey noted in her Concurring and Dissenting Statement in *Cliffdale Associates, Inc.*, Docket No. 9156 (March 23, 1984), she believes the elements of deception are that an act or practice have the tendency or capacity to mislead a substantial number of consumers in a material way. She did not endorse the Commission's *Cliffdale* description (slip op. at 7) of the elements of deception nor does she endorse it in this opinion. However, Commissioner Bailey agrees that respondent's practices in this case were deceptive under either description of the term. [103 F.T.C. 110 (1984)]

[5] *Id.*

[6] This is the only issue we look at. We do not additionally consider whether the advertiser intended to deceive consumers with the claim, or whether an objective product claim (*i.e.*, one not involving puffery or subjective value

(footnote cont'd)

judgments) is so far-fetched that reasonable consumers would not believe it. Thus, if an ad expressly claims that a shampoo will cure baldness, we presume that reasonable consumers would be deceived by the ad. We presume this even though we might think few people are unaware of the fact that there is no cure for common baldness. *See, e.g., Keele Hair & Scalp Specialists, Inc.* 55 F.T.C. 1840 (1959), *aff'd* 275 F.2d 18 (5th Cir. 1960).

[7] Advertisements do not necessarily convey one message to all persons. One subset of consumers reading an ad may interpret it to contain one message, while another subset may interpret it to contain a different message. Each interpretation is reasonable so long as the subset making it is representative of the group of persons to whom the ad is addressed. *See, e.g., Heinz W. Kirchner*, 63 F.T.C. 1282, 1290 (1963).

[8] This longstanding principle of Commission case law was most recently reiterated by us in *Bristol-Myers Co.*, 102 F.T.C. 21, 319 (1983), *aff'd* 738 F.2d 554 (2d Cir. 1984), *petition for cert. filed* No. 84-[illegible], a case involving deceptive advertisements for OTC internal analgesic products: "There also may be [illegible] where claims cannot be inferred from a facial examination of the advertisements and resort to [illegible] evidence is necessary. *See, e.g., Leonard F. Porter, Inc.*, 88 F.T.C. 546, 626 (1976)."

[9] Similarly, past Commission cases recognize that affirmative disclosures can be an effective [illegible] preventing consumer misunderstanding of ads. However, Commission cases also recognize that such [illegible] need to be made clearly and prominently to be effective. Whether or not a particular disclosure was [illegible] is a question for whose answer we often would seek information in addition to that from the ad itself. However, where a simple inspection of the ad leaves us confident that the disclosure was ineffective for [illegible] we will not require extrinsic information. [illegible]

Another type of evidence we will look at is evidence not specifically showing how consumers understood the advertisements at issue before us, but showing how consumers might ordinarily be expected to perceive or understand representations like those contained in the ads we are reviewing. For example, we might look at the dictionary definition of a word to identify the word's common usages. Or we might look at principles derived from market research, as expressed by marketing experts, which show that consumers generally respond in a certain manner to ads that are presented in a particular way, and presume that consumer reactions to a particular ad before us would be consistent with the general response pattern. Where we apply such marketing principles, we will derive them from research presented in references generally accepted as reliable in the field of marketing. Such references may be cited by marketing experts called to testify in the proceeding. Alternatively, we may take official notice of the references and cite to them directly in our opinion. [10]

A third type of evidence we will consider if offered is the opinion of expert witnesses in the proceeding as to how an advertisement might reasonably be interpreted. For example, we might consider the opinion of a marketing expert who stated his or her view that consumers would interpret an ad in a particular manner. However, where the opinions voiced by experts are not adequately supported we ordinarily give them little weight.[11]

Whether we are looking at evidence from the ad itself, extrinsic evidence, or both, we look at the overall, net impression made by an ad to determine what messages it reasonably can be interpreted as conveying to consumers.[12] For example, we would look here at whether or not consumers thought, after viewing Thompson's television ads, that Aspercreme contains aspirin. We would not look at how consumers reacted to a particular element from the ad in a different context than the ad itself.

In this case, Thompson has acknowledged making several of

the represenations listed in the complaint (RMF 142–43). These are: [11]

Complaint Paragraph Number	Alleged Representation
12(a)	Aspercreme is an effective drug for the relief of minor arthritis and its symptoms.[13]
12(b)	Aspercreme is as effective a drug as orally-ingested aspirin for the relief of minor arthritis and its symptoms.
12(d)	Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms.
12(e)	Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder.[14]

Because Thompson has acknowledged making the above-listed representations, we may state without reviewing the ads that Thompson intended to make these claims. Therefore, it is reasonable to interpret the ads as making them. [12]

Thompson has not acknowledged making any of the other representations listed in the complaint. We therefore examine each of these alleged representations in turn to determine whether or not consumers acting reasonably under the circumstances would interpret Thompson's advertisements as making them.

2. *Aspirin Content—Paragraphs 10(a), 16.*

Of all the disputed representations, the one that received the most attention at trial was the issue of whether or not Thompson's advertising, and specifically the trade name "Aspercreme" represented that the product contains aspirin. Complaint counsel argued that it did, *i.e.*, that it represented Aspercreme to contain a cream form of acetylated salicylate, as aspirin is defined in the United States Pharmacopoeia. Thompson argued that the ads merely suggest Aspercreme is a drug which works like the more familiar aspirin, not that it actually contains aspirin (RAB 41). Thompson also argued that consumers understand the word "aspirin" as a generic reference to the class of drugs that are pain killers, not to the particular salicylate contained in aspirin tablets (RAB 35–36). Thus, the issues presented for our consideration here are, first, whether one net impression it is reasonable to interpret Thompson's ads as conveying to consumers is that Aspercreme contains aspirin and, second, what consumers would interpret the word "aspirin" to mean in the context of the Aspercreme ads. [13]

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[10] See, e.g., our discussion of survey methodology in *Bristol Myers Co.*, 85 F.T.C. 688, 744 n.14 (1975).

[11] We consider to be adequately supported opinions that describe empirical research or analyses based on generally recognized marketing principles or other objective manifestations of professional expertise. Opinions not so supported may easily be contradicted by the contrary opinions of opposing experts and thus may be of little [illegible] in resolving the issue.

[12] See, e.g., *Bristol Myers*, supra note 8, at 320; *Horizon Corp.*, 97 F.T.C. 464, 810 (1981).

[13] In acknowledging that it made this claim for relief of arthritis, Thompson denied representing that Aspercreme will cure the disease. Thompson similarly denied representing that Aspercreme will cure rheumatism. The ALJ found that Thompson had not made such representations (ID's 131-32, 141-42).

[14] We note that the complaint included another allegedly deceptive representation. Complaint Paragraph 12(f) charged Thompson with representing that Aspercreme does not result in the adverse reactions associated with aspirin. The ALJ concluded (IDF 119) that in the context of Thompson's advertisements, the statements about "no side effects" would be taken to mean "no significant" side effects, for which [illegible] Thompson [illegible] reasonable basis. [illegible] the ALJ dismissed [illegible] Paragraph 12(f). We agree with the ALJ's disposition of this part of the complaint.

We note to begin that none of the Aspercreme ads includes an express representation that Aspercreme contains aspirin. On the contrary, like much advertising we find deceptive, the ads are drafted with an artful choice of words to make what Thompson thought were literally correct statements (for example, that Aspercreme's pain relieving properties are equivalent to aspirin's). However, in considering the net impression of an advertisement, we do not require that all consumers reading or viewing it be sophisticated experts in interpreting the nuances of the English language. Absent reason to conclude differently, we presume that advertisements are directed at ordinary members of the adult population who, as such, have a range of abilities.[15] We look at how such [14] individuals actually interpret advertisements in real-life situation, not at how they would if they had sufficient time and incentives attentively to review the ads so as to come up with the most semantically correct interpretation of them. We therefore consider here whether one message impliedly conveyed to reasonable consumers by the ads is that Aspercreme contains aspirin. To do this, we need to evaluate the ads' net impression on consumers. The ads are not all alike; rather they fall into several different groups. We describe each group below and consider whether it gives a net impression of aspirin content.[16]

(1) The TV Ads With No Disclosures—CXs 1 and 2

Thompson's earliest television ad for Aspercreme, CX 1, shows a woman talking. As the ad begins, she is shown holding two aspirin tablets and saying ". . . imagine being able to put the strong relief of aspirin right where you hurt most." At this point, the two aspirin tablets in her hand disappear and are replaced by a tube of Aspercreme, while she says: "Now, with amazing Aspercreme, you can get

the strong relief of aspirin directly at the point of minor arthritis pain." She continues comparing Aspercreme to aspirin, noting (among other things) that Aspercreme contains none of aspirin's side effects. As the ad ends, she leaves the screen and is replaced by a still life [15] showing a tube and bottle of Aspercreme, along with a video super stating: "The strong relief of aspirin right where you hurt." The audio portion of the ad concludes with a voice over stating the same phrase as the video super.

The second early Aspercreme ad, CX 2, is similar to CX 1 at its beginning and end. To begin, it shows a woman holding two aspirin tablets. As she holds the tablets, she tells listeners to "imagine putting the strong relief of aspirin right where you hurt." Next an Aspercreme tube replaces the two tablets, whereupon she states: "Aspercreme is an odorless rub which concentrates the relief of aspirin." At this point, CX 2 diverges from CX 1. In its middle portion, CX 2's visual part uses the transparent outline of a man's body and rays streaming outward from both an aspirin tablet in the stomach and a point on the shoulder where Aspercreme was rubbed. There are fewer rays from the stomach than from the shoulder. As the rays are shown visually, the woman states that "regular aspirin . . . goes through your body like this [through the stomach]. But, in seconds, Aspercreme starts concentrating all the temporary relief of two aspirin directly at the point of minor arthritis pain." The ad concludes with the same still life and audio as does CX 1. [16]

The ALJ concluded that a variety of different elements in these ads were representations that Aspercreme contains aspirin.[17] Among the elements were use of the brand name "Aspercreme," repetition of the words "Aspercreme" and "aspirin" in the same commercial, use of the statement that Aspercreme provides "the strong relief of aspirin" and the visual image in which two aspirin tablets are replaced by a tube of Aspercreme (IDFs 85–89).

Our own examination of the net impressions conveyed by these ads also causes us to conclude that they suggest that Aspercreme contains aspirin. We agree with the ALJ's view that various elements in the ads suggest aspirin content. We further note the absence of any elements giving a contrary impression, such as express disclosures. Therefore, all the evidence from the ads themselves points to one conclusion: that the ads are likely to give consumers interpreting them reasonably a net impression that Aspercreme contains aspirin.

Although we do not find it necessary from our perspective to look at extrinsic evidence in evaluating CXs 1 and 2, Thompson has offered some in support of its theory that consumers would interpret CXs 1 and 2—and all the other Aspercreme ads, as well—to mean that Aspercreme provides relief like aspirin [17] without actually containing aspirin as an ingredient (RPF 240–60). Because Thompson offered extrinsic evidence, we are obliged to consider it. However, our review of Thompson's evidence does not change our views regarding CXs 1 and 2.

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[15] If advertisements are targeted at special audiences who as a group have a greater or lesser capability to recognize deceptive advertising than ordinary members of the adult population or a distinctive reaction to particular advertising claims, a reasonable consumer is an ordinary member of that target audience. *See, e.g., Travel King,* 86 F.T.C. 715 (1975). However, almost all advertising is targeted at some demographic group, such as farmers, housewives, or residents of a particular area. This alone does not mean that we apply a standard different from our customary one.

Previous Commission cases have recognized that persons with health-related problems can be a target audience. *See, e.g., Travel King, id.; Porter & Dietsch,* 90 F.T.C. 770, 864-65 (1977), *aff'd,* 605 F.2d 294 (7th Cir. 1979), *cert. denied,* 445 U.S. 950 (1980). In this case, Thompson's ads were directed at arthritics. The ALJ's opinion (IDF 90) suggests that he considered arthritics to be a target audience. Though his finding was stated in conclusory fashion, other available evidence and findings such as the fact that arthritis is a chronic disease (IDF 191) and that consumers spend significant amounts of money on quack remedies (IDF 193) suggests that arthritics may be more susceptible to deceptive analgesic claims than ordinary members of the adult population and therefore are a target audience. Ultimately we find it unnecessary to resolve the question because the evidence in this proceeding shows that Thompson's ads were deceptive whether or not arthritics are considered a target audience.

[16] Our discussion here focuses solely on the advertisements Thompson used in the national consumer advertising campaign for Aspercreme (CXs 1-11, 21-22, and 27). We do not evaluate the Aspercreme use in the local Ohio market (CXs 12-20) because our conclusions about the national ads makes it unnecessary to do so.

[17] The ALJ did not distinguish between express and implied representations. He also did not focus separately on the net impressions given by CXs 1 and 2. Rather, he analyzed whether or not individual words, phrases, or visual images used in one or more of Thompson's ads implied aspirin content. As we noted in the text, above, our method of analysis looks at the net impression created by the interaction of different elements in a given ad, not at the elements by themselves.

One type of extrinsic evidence offered by Thompson consisted of testimony by marketing experts. (*See, e.g.*, Ross, Tr. 5963–68; Jasper, Tr. 4736; Silver, Tr. 5654–55) and the results of a consumer survey, the Video Storyboard Test (RX 165). Having examined the testimony, we find it unpersuasive.[18] [18]

Thompson also has claimed that the results of the Video Storyboard Test (RX 165) show that CXs 1 and 2 do not leave a net impression of aspirin content with consumers who interpret the ads reasonably. The Video Storyboard Test is, of course, consumer survey research, and as such is the type of evidence to which we would give considerable weight if it were methodologically sound. However, we agree with the ALJ's conclusion (IDF's 117–19) that the Video Storyboard Test was improperly designed for the objective of providing data on whether CXs 1 and 2 communicate a net impression of aspirin content to consumers.

Although the report of the Video Storyboard Test does not include a protocol describing what the study was designed to measure and how the methodology chosen would do so (in and of itself a factor we view negatively when assessing the quality of a study), it appears that the survey was designed to measure the comparative effectiveness of CX 1 and CX 2 in conveying important attributes of Aspercreme to potential users (RX 165A-M). In order to collect this information, the Video Storyboard Test used a shopping mall intercept sample to obtain 100 participants. The respondents were qualified by age, *i.e.*, 45 years and older, and by whether they "occasionally have symptoms of arthritis" (CX 165-O). Fifty participants were shown CX1 and the other fifty viewed CX 2. Immediately after viewing either CX 1 or CX 2, participants completed the survey questionaire.

Although the sample was a non-probability sample (*i.e.*, its results are not projectable to the national population as a whole) and rather small, there is no apparent reason why the [19] persons surveyed would not be reasonably representative of a typical subset (those over 45 who suffer occasional symptoms of arthritis) of those persons who generally might be interested in purchasing analgesics to relieve arthritis pain. However, CX 51 does not provide probative information about the participants' beliefs about aspirin content in Aspercreme for two reasons. First, it does not contain any questions that directly elicit ingredient information. Second, the verbatim responses were not placed on the record and the data from the study were not coded to determine the percentage of responses that included mentions of ingredients (Ross, Tr. 6310). The questionnaire used in the Video Storyboard Test was concerned with the persuasiveness of each commercial (question 1), the impact of the messages or copypoints in each commercial (questions 2, 3, 4, 9, 10, 11 and 12), the perceived uniqueness of Aspercreme (questions 5 and 6), the relative effectiveness of Aspercreme compared to aspirin (questions 7 and 8), and demographics (age and sex of respondents). The way in which these questions were phrased makes any information provided about ingredients in general, and aspirin content in particular, incidental to the information gathered about the relative effectiveness of CX 1 and CX 2 as commercials. Of course, some participants nonetheless may have mentioned ingredients in their responses to the questions being asked. If the record contained information showing how many participants gave such responses, we would examine whether enough had done so to make the results reasonably reliable. However, no [20] such information was supplied with CX 51. Therefore, we find that CX 51 is of no probative value in determining the consumers' beliefs about whether Aspercreme contains aspirin.

While we thus find the extrinsic evidence relied on by Thompson not to be probative, we find that complaint counsel's evidence does not provide extrinsic evidence consistent with the conclusions we reach from analyzing the ads themselves. Complaint counsel cite to the Mapes and Ross Test (CX 50), which was conducted for Thompson in 1979, prior to the start of this litigation. Although Thompson now criticizes the design of this survey (RAB 53–54), we find that its methodological strengths far outweigh its weaknesses. Specifically, its research methodology (or close variants of it) is frequently used in copytests. For example, the use of prerecruited groups of subjects, lotteries to provide incentives for viewing, the attempts to "bury" the commercials in programmatic material, and day-after unaided recall, aided recall and brand preference measures are typical of advertising copytests. In addition, although the study did not employ a probability sample and discussed neither survey response rates nor non-response bias, we cannot detect any obvious reason why the sample is not reasonably representative of consumers viewing CXs 1 and 2. Such methodology is adequate for the results to be of some probative value, assuming the survey asked probative questions.

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[18] For example, Thompson's principal marketing expert, Dr. Ross, speculated on whether the percentage of consumers coming away from CXs 1 and 2 with the impression that Aspercreme contains aspirin rose above an irreducible minimum, but he provided little factual or analytical support for his observations." *See e.g.*, Tr. [illegible]

Q. Is it possible, Dr. Ross, that some consumers might have taken away the impression from CX-1 that Aspercreme is aspirin?

A. Yes. I think it is possible. I think that some may have and I think that that impression would occur simply from the analogy between Aspercreme and internal analgesics. That is, some may think of it relieves the same way as it is aspirin.

But I think that is a kind of irreducible minimum percentage kind of thing of a perception, of a misperception, so that I think if you are going to compare any external rub product to any internal product, any internal analgesic product, that some are going to assume that you mean aspirin, since that is the word that they use for such internal tablets or product.

So, in perceiving that the ad is representing that Aspercreme has aspirin, all the consumer is really thinking or saying is that it has an analgesic in it.

Like the Video Storyboard Test, the Mapes and Ross survey contained questions that attempted to elicit participants' recall of the information contained in CX 1 and CX 2 and did not contain direct questions about ingredients. However, unlike the Video [21] Storyboard Test, the Mapes and Ross final report contains the verbatim responses provided by the participants so that the percentage of respondents who mentioned aspirin as an ingredient can be determined. From the resulting responses come two estimates of the percentage of relevant market females who, given one exposure to a televised Aspercreme commercial, perceive that Aspercreme contains aspirin. The first estimate is contained in the Mapes and Ross final report, which calculates the percentage of survey participants who thought Aspercreme "Works Like/Contains Aspirin" after viewing CX 1 or CX 2. The second estimate is contained in a memo from an Ogilvy and Mather researcher who reviewed the verbatim transcripts of the data collected in the study and independently calculated the percentage of respondents who believed Aspercreme contained aspirin (CX 116–A). The data from both sources are provided below:

Table 1

Respondents Perceiving:	CX–1 Visible Man %	CX–2 Stand-Up Presenter %
Aspercreme "Works Like/Contains Aspirin" (CX50–H)	23	35
Aspercreme product contains aspirin-recallers only. (Ogilvy and Mather memo, CX116–A)	21	30 [22]

Although there are some biases in the Mapes and Ross Test,[19] its results support our conclusion that one reasonable interpretation

consumers would make of these two ads is that Aspercreme contains aspirin.

Thus the Mapes and Ross Test, the only reasonably reliable extrinsic evidence regarding CX 1–2, supports our conclusion that it is reasonable for consumers to interpret CXs 1 and 2 as making an implied claim of aspirin content.

(2) The TV Ads With Visual Disclosures—CXs 3 and 4

The next two Aspercreme television ads, CXs 3 and 4, are essentially similar to the earlier ads, CXs 1 and 2 respectively, with one difference. Both CX 3 and CX 4 have video supers that read: "contains no aspirin." Thus, the question presented by CXs 3 and 4 is whether the video supers are sufficiently clear [23] and conspicuous to overcome the impact of other elements in the ads, elements which caused somewhere between 21% and 35% of the persons viewing CXs 1 and 2 to believe that Aspercreme contains aspirin.

The extrinsic evidence relating to CXs 3 and 4 is not of the sort we perfer to rely on in evaluating the possible existence of implied claims, but is sufficient for us to reach the conclusion that the ads' net impression upon reasonable consumers is one of aspirin content. There is no survey research pertaining directly to CXs 3 and 4, and we are not persuaded by the expert opinions presented at trial as to what consumers would interpret the ads to mean (*See* Cohen, Tr. 213–18; Ross, Tr. 6016–18, 6185–98) because we find them to be inadequately supported.[20] However, copy testing performed on an Aspercreme ad with what appears to be a more prominent disclosure of non-aspirin content, CX 9, found that one net impression given to consumers was that the [24] product contains aspirin.[21] CX 9 was sufficiently similar to CXs 3 and 4 that we consider it permissible to infer from the CX 9 results that an even higher percentage of consumers would come away with such a net impression after watching CXs 3 and 4.

Additional extrinsic evidence in the form of generally recognized marketing principles also leads to the conclusion that the disclosures were insufficiently clear and conspicuous. The disclosures were placed in the middle of the ads and were distracted from by the conceptually uncorresponding audio message being communicated while they were on the screen. Studies of consumer behavior show that individuals will better remember either information presented to them first (primary effect) or information presented to them last (recency effect), depending upon the delay between presentation of the messages and evaluation of the recipients' responses. In any event, however, recall typically is a U-shaped function, with the worst recall being of messages presented in the middle. A distracting situation lowers ability to recall at all points along the curve.[22] [25]

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[19] The test contains several potential sources of bias which may have affected the estimate of the percentage of people who believe Aspercreme contains aspirin. On one side, the screening process used to obtain the sample may have alerted participants about the nature of the study. If so, respondents would have paid more attention to the commercials than they otherwise might have. On the other side, one exposure to the advertisements is less than the three recommended for maximum recall and comprehension in a natural viewing situation. *See* H. Krugman, *Why Three Exposures May Be Enough*, Journal of Advertising Research, Dec. 1972, 11–14. The omission of aided questions or probes about ingredients probably caused the estimates of the proportion of respondents believing that Aspercreme contained aspirin to be understated.

[20] The ALJ's initial opinion also cites the views of CBS and the National Association of Broadcasters (NAB) that the disclosures were inadequate as evidence that the disclosures were so. The opinion does not clearly [illegible] to the ALJ's ruling at trial (Tr. 637) that the opinions of CBS and NAB were to be admitted into [illegible] not as primary evidence, but only as confirmatory evidence (Tr. 637). (The opinion does describe the CBS and NAB views as "confirmatory", but fails to indicate that the word has any special significance.) We agree with the ALJ's view at trial that this evidence cannot be relied on to establish in the first instance whether or not the video supers were adequate. As was argued by Thompson (Tr. 631–36), the record does not show the qualifications of the individuals at CBS and NAB who reached the conclusion that the supers were inadequate, the facts that were before these individuals, or the standards they applied to the facts. However, we see no logical basis for the ALJ's decision to use these opinions as "confirmatory" evidence and, accordingly, do not rely upon them ourselves.

[21] *See our discussion* of CX 9, below at pp. 11–12.

(3) The Print Ads With Common Headlines—CXs 6–7, and 10–11.

Six print ads for Aspercreme were introduced into evidence in this proceeding. Four of them, CXs 6–7 and 10–11, have common elements. Principal among these is an identical headline. The ads begin in large print:

> At last! A remarkable breakthrough
> for arthritis pain: Aspercreme.

Below this and in smaller print, the headline continues:

> Aspercreme is an effective arthritis medicine
> which concentrates all the strong relief of aspirin
> directly at the point of pain.

All four ads also contain a visual representation of an Aspercreme tube and bottle. Both display the brand name "Aspercreme" and the statement, "external arthritic pain medication."

Two of the ads, CXs 6 and 7, have additional elements that would contribute to their net impression concerning aspirin content. Below their headlines, each shows a drawing of a man's body, with numbered lines pointing to various body parts. Associated with each line is text in smaller print that the headlines. CX 6's text compares Aspercreme to aspirin in two ways: (1) "Aspirin tablets go through your body. But Aspercreme concentrates the relief of an effective aspirin-like analgesic [26] directly at the point of arthritis pain . . ."; and (2) "Aspercreme, like aspirin itself, has no liniment smell." CX 7's text has three comparisons between Asprecreme and aspirin: (1) "Aspirin tablets go throughout your body. But Asprecreme concentrates the relief of two aspirin directly at the point of arthritis pain . . ."; (2) "Aspercreme works faster than aspirin because you rub it right where you hurt"; and (3) "Aspercreme, like aspirin itself, has no liniment smell."

We conclude that it would be reasonable to interpret all four print ads as conveying a message of aspirin content. For three of the ads, CXs 7, 10–11, we reach this determination based solely upon our examination of evidence from the ads themselves. In particular, we conclude that the language in the headline ("Aspercreme . . . concentrates all the strong relief of aspirin . . .") is readily susceptible to the interpretation that Aspercreme contains aspirin and that the language would be so interpreted by consumers. Given this fact, and given that no other elements in these ads suggest other than that Aspercreme contains aspirin, we conclude that at least one of the net impressions communicated by the ads is of Aspercreme's aspirin content.

One of the ads, CX 6, does include textual language amounting to an implied representation that Aspercreme does not contain aspirin. It states: "Aspercreme concentrates the relief of an effective aspirin-like analgesic . . ." The most direct conclusion to draw from a statement that Aspercreme is "like" aspirin would be that it is similar to but not the same as aspirin. Because this element in the ad conflicts with the [27] element stating that Aspercreme "concentrates all the strong relief of aspirin," we require something in addition to evidence from the ad itself before determining whether or not consumers would interpret CX 6 to state that Aspercreme contains aspirin.

The additional element in the case of CX 6 is the general marketing principle, acknowledged by Thompson's marketing expert (Ross, Tr. 6198–99) as well as complaint counsel's (Cohen, Tr. 223), that persons reading a print ad often will read only the headline, and will take their sole impression of the ad from it. The special significance of headlines has previously been recognized in Commission cases, which hold that even an express disclosure in the text of an ad may not be enough to change the ad's net impression upon consumers.[23] Applying this principle to CX 6, complaint counsel's marketing expert testified that a great many people reading CX 6 would believe Aspercreme to contain aspirin (Cohen, Tr. 233).[24] We also find that application of the general principle to this specific situation suggests such a [28] result. Upon this basis, we conclude that one net impression consumers reasonably would understand CX 6 to be conveying is that Aspercreme contains aspirin.

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[22] See B. Sternthal and C. Craig, *Consumer Behavior, An Information Processing Perspective* 102-03, 292-93 (1982) and works cited therein.

[23] See, e.g., *Litton Industries, Inc.*, 97 F.T.C. 1, 70 n.5 (1981); *Giant Food, Inc.* 61 F.T.C. 326, 348–49 (1962), *aff'd* 322 F.2d 977 (D.C. Cir. 1963), *cert. denied*, 376 U.S. 967 (1964).

[24] Thompson's marketing expert argued that the headline itself does not imply aspirin content (Ross, Tr. [illegible]), from which it would follow that persons reading the headline alone would not believe Aspercreme contains aspirin. While we are obliged to consider this opinion because it was offered as evidence, we find it unpersuasive.

(4) The Other Print Ads—CXs 8, 37.

The other two print ads, CXs 8 and 37, are different from the other four and from each other. We first examine CX 8.

Beginning with its headline, CX 8 repeatedly contrasts Aspercreme with aspirin. The headline states:

> There's always been aspirin . . .
> Now there's ASPERCREME[35]
> Works faster, safer than aspirin—relieves pain in minutes.

The first sentences of the text, (in considerably smaller print than the headline) continue this comparison approach by stating: "Aspirin has been helping sufferers of minor arthritis pain for years. Now there's a different way to get relief. ASPERCREME." Other comparisons in the text similarly contrast Aspercreme with aspirin. In addition, there is a visual depiction of an Aspercreme tube in its display packaging. Visible on the display packaging, in print slightly smaller than the text of the ad, is the statement: "An effective aspirin-like analgesic for temporary relief of occasional minor pain . . ." [29]

We are not able to conclude with adequate confidence by looking solely at evidence from the ad itself whether or not one message conveyed to consumers by CX 8 is that Aspercreme contains aspirin. The general tone of the ad contrasts Aspercreme with aspirin, emphasizing the supposed difference between the products rather than their similarities.[36] These contrasts might create among average consumers the impression that Aspercreme is different from aspirin. On the other hand, it might also be that the perceived difference would be means of application (external rather than internal), not identity of active ingredients.

In this situation, we cannot find the ad to convey an implied message without sufficiently probative extrinsic evidence upon which to base our conclusions. We do not find any such evidence here. There was no consumer survey research on CX 8 or any other Aspercreme advertisement similar enough to CX 8 to permit the drawing of inferences about CX 8 from it. The testimony of the marketing experts also does not permit us to reach reasonably confident conclusions. Complaint counsel's principal marketing expert argued that most people looking at a newspaper ad such as CX 8 would only look at the headline, which links Aspercreme with aspirin (Cohen, Tr. 226), but he did not show that the link created by such a headline would equate Aspercreme and aspirin; instead, consumers might interpret the link to suggest that Aspercreme is a new product similar to but [30] different from aspirin.[37] Thompson's principal marketing expert, on the other hand, emphasized the fact that CX 8 contrasts Aspercreme with aspirin, concluding from this that if consumers understand aspirin as a specific ingredient, the headline would communicate that Aspercreme is not aspirin (Ross, Tr. 6026–27). However, he provided no evidence to exclude a possible consumer interpretation of the headline that Aspercreme provides the clinically active ingredient of aspirin tablets in a cream form. While both sides have thus failed to present adequate extrinsic evidence concerning CX 8, the burden was on complaint counsel to do so. In light of that failure, we cannot find CX 8 to contain an implied message of aspirin content.

We next turn our attention to the remaining print ad, CX 37. The headline of CX 37 characterizes Aspercreme as "a remarkable analgesic" and as "an effective alternative to pills for minor arthritis pain." The first paragraph of the text, which is in bolder print than the remainder, states: "Aspercreme contains salycin, an effective *non*-aspirin pain reliever that concentrates relief right at the point of pain. You get hours of relief without the side effects pills may cause." Further on, the text additionally states: "Aspercreme has a *non*-aspirin pain reliever, so it can't cause aspirin's stomach upset or any of aspirin's side effects" and "Aspercreme's active pain reliever—[31] *salycin*—is clincally proven . . ." (emphasis in original). All of these elements suggest a difference between the active ingredient in Aspercreme and the active ingredient in aspirin. Nor is there any element in the ad except for the brand name that even arguably could be viewed as implying that Aspercreme and aspirin are the same. It may be that the brand name alone would be enough to convince some readers that the product contains aspirin, and that the disclosures would be insufficient to overcome this misimpression. However, we would require that such a conclusion be supported by extrinsic evidence.

Our conclusion diverges from the ALJ's, who found that CX 37 did represent aspirin content (IDF 84). However, the ALJ's discussion of this particular ad is flawed by his analytic approach, which was to look at each element that was in one or more ads and then to decide whether or not the element, considered by itself, represented aspirin content. Not only do we believe this approach to be less analytically desirable than considering the net impression which different elements in an ad combine to give, but in this case the approach caused the ALJ to lump CX 37 together with several of Thompson's television advertisements, all of which are quite different from CX 37. Thus, the

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[35] This part of the headline is in significantly larger print than other parts.

[36] The other Aspercreme ads we have reviewed up to now emphasized similarities, e.g., "aspirin's relief."

[37] We will not presume generally that consumers interpreting advertisements reasonably under the circumstances will always read a comparative ad to imply that the products being compared are the same. For example, we seriously doubt that persons reading "Buy a racing car. It provides faster, more enjoyable transportation than a station wagon." would interpret the ad to imply that the products were the same.

ALJ incorrectly wrote that the affirmative statements in several ads, including CX 37, were required by the television networks. Obviously, the networks had no control over print ads such as CX 37. Likewise, where the ALJ cited extrinsic evidence as to why the affirmative statements in various ads were ineffective disclosures (IDF 84), the evidence itself pertained only to the television advertisements, not to CX 37 [32]

The one point made by the ALJ that appears specifically to apply to CX 37 is his observation that the phrase "contains salycin, a non-aspirin pain reliever," found in both CX 37 and several television ads, is ambiguous because it does not negate the impression that Aspercreme may contain *both* aspirin and "salycin." We find this point unpersuasive for two reasons. First, while it is literally true, as a nicety of English semantics, that the statement "contains salycin" would not absolutely negate the possibility that Aspercreme also contains aspirin, nothing in CX 37 expressly states that Aspercreme has more than one active ingredient. Nor do we find that the brand name "Aspercreme" or any other element in CX 37 implies the product contains two active ingredients.[20] Therefore, in considering how consumers probably would interpret the ad, rather than how it is technically possible for someone to read it, we find it irrelevant that the statement in CX 37 does not specifically exclude the possibility of two active ingredients. Second, even if one thought average adults were sticklers for English semantics, there is a statement in CX 37, one which the ALJ overlooked, that does negate the possibility of aspirin content. It is the statement that Aspercreme's "active pain [33] reliever" is salycin. Since the ad refers to "pain reliever" in the singular, it excludes the possibility of there being a second active ingredient.

(5) The TV Ads With Audio Disclosures—CXs 5, 9 and 21-22

The most recent television ads for Aspercreme, the ones on which most of the Aspercreme advertising dollars were spent (CX 25A), contain audio disclosures that either expressly or impliedly state that Aspercreme does not contain aspirin. Three of the ads, CXs 5, 9 and 21, are testimonials whose main focus is to show various men and women endorsing the product. Among the individuals' statements are those that Aspercreme relieved their arthritis, did not upset their stomachs, was odorless, or relieved their pain for hours. These ads do not mention the word "aspirin," liken Aspercreme's relief to that provided by aspirin, or liken Aspercreme to "pills." Each also contains a disclosure in a middle frame of the ad (rather than at its beginning or end) stating that Aspercreme does not contain aspirin. In CX 5, it

is the express audio statement "aspirin free," coupled to a visu image of an Aspercreme tube. In CXs 9 and 21, it is the stateme "Aspercreme contains salycin, a strong non-aspirin pain reliever coupled to the visual image of an Aspercreme tube and the vid super "contains salycin."

In the remaining TV ad, CX 22, a woman compares Aspercrem with "pills," stating that Aspercreme provides long lasting reli without the side effects pills may cause. Insofar as "pills" is an im plied reference to aspirin tablets, CX 22 is an [34] ad that contras the two forms of medication. In the middle frames of the ad th woman states "Aspercreme relieves arthritis pain because it contain salycin, a strong non-aspirin pain reliever." while the visual porti of the ad shows her applying Aspercreme to the back of one of h hands.

We would not find CXs 5, 9 and 21-22 to convey an implied aspiri content message if we were to rely solely upon an examination evidence from the ads themselves. The contradictory elements i these ads preclude us from determining with sufficient certainty wha message(s) viewers would take away from the ads concerning th aspirin content of the product. On the one hand, there is no discl sure that Aspercreme contains a non-aspirin pain reliever, coupled t the absence of any language or visual imagery likening the produc to aspirin tablets. On the other hand, there is the "Aspercreme brand name itself. The brand name was visually displayed in each ad as well as being repeated beween four and six times on the ads' voic tracks. Moreover, the brand name of a product is the most powerfu single stimulus in an ad. Consumers are more likely to recall bran names than specific copy points in advertisements (Cohen, Tr. 55 Ross, Tr. 6317-19). A net impression based primarily upon a messag derived from the brand name could be that Aspercreme contain aspirin.

In this situation, we require extrinsic evidence to help us determin how reasonable consumers actually perceive the ads. The record con tains three surveys that we believe shed light on the question of wha consumers believe CX 9 to mean: the FRC Test (CX 35/RX 520), an the Lieberman Test (CX 32/RX 500), which [35] were both sponsore by Thompson, and the ASI Theater Test (CX 27), which was sponsor by complaint counsel. The results from each of these studies an significant details about their methodologies are summarized below However, the conclusion we draw from the surveys can be stated a the outset: consumers interpreting CX 9 reasonably could and d think that Aspercreme contains aspirin.

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[20] The name "Aspercreme" may imply that Aspercreme contains aspirin as an active ingredient. However, the name does not suggest whether or not the product has more than one active ingredient.

(a) *The FRC Test (CX 35/RX 520) and the Lieberman Test (CX 32/RX 500)*

In 1981 Davis and Gilbert, Thompson's counsel, contracted with Ken Warwick and Associates, Inc. to design a copytest of CX 9. Based on background information contained in the FTC complaint and discussions with Davis and Gilbert, Warwick designed and conducted the FRC copytest (CX 35/RX 520). After the FRC study was completed and the results were in, Warwick redesigned the survey questionnaire used in CX 520 and completed a second study, the Lieberman copytest (CX 32/RB 500).

Both the FRC and Lieberman studies were intended to determine the percentage of respondents who, after viewing CX 9, believed Aspercreme contained aspirin. The methodology was the same for both studies and involved showing respondents, who were recruited and screened with shopping mall intercepts, the advertisement CX 9 and asking them a short series of questions. Respondents were shown CX 9 twice and no distracting materials such as other ads were included. This methodology increases the probability that respondents paid attention to CX 9. Thus, if [36] there was any bias in the methodology used in the Warwick studies, it was in the direction of increasing the percentage of respondents who remembered the information presented in CX 9.

Although there were few differences in the research design between the FRC and Lieberman studies, there were important substantive differences in the survey questionnaires used in each study. The questionnaire in the first study contianed four questions probing consumer perceptions as to the ingredients of Aspercreme and two other analgesic rubs:

> Q1. First, what was the name of the ingredient in the product you just saw advertised?
> Q2. Based on the commercial you just saw, does the product in the commercial contain aspirin?
> Q5. Does Ben-Gay contain aspirin?
> Q6 Does Mentholatum contain aspirin? (RX 520; Warwick, Tr. 5332)

The second study contained only one question probing such consumer perceptions:

> Q1 What was the name of the ingredient in Aspercreme, the product advertised? (RX 500-E)

Findings from the FRC and Lieberman studies are summarized in Table 2: [37]

Table 2
Unaided and Aided Recall Results to
Questions About the Ingredients in Topical Analgesics

Ingredients Mentioned With Unaided Recall	FRC Survey Question 1*	Lieberman Survey Question 1**
Salycin	95 (45.9%)	(25%)
Aspercreme	43 (20.8%)	(2%)
Aspirin	6 (2.9%)	(5%)
Blank/Don't Know	47 (22.7%)	(65%)
Others	16 (7.7%)	(3%)
n (totals)	207 (100%)	212 (100%)

Aided Recall Perception of Whether Aspirin is an Ingredient in...*	FRC Survey Yes	No	Don't Know	Total
Aspercreme (question 2)	22.2%	67.6%	10.1%	99.9%
Ben-Gay (question 5)	6.3%	39.1%	54.6%	100.0%
Mentholatum (question 6)	4.8%	43.5%	51.7%	100.0%

*RX 520-G
**Warwick, Tr. 5321.

The results from the unaided recall questions (the first question contained in each survey) indicate that between 25 and 46 percent of the participants identified Salycin as the ingredient in [38] Aspercreme. Thus, less than half of the respondents were able to provide this response after seeing the commercial twice. However, in both surveys very few of the respondents mentioned aspirin as an active ingredient in Aspercreme. Thus, the unaided recall question in both surveys tends to support Thompson's position.

The results from the aided recall questions in the FRC survey (questions 2, 5 and 6) tell an entirely different story. That is, when queried directly about whether Aspercreme contains aspirin, 22 percent of the respondents replied affirmatively. Conversely, only 6 percent of the respondents thought aspirin was an ingredient in Ben-Gay and less than 5 percent perceived that aspirin was contained in Mentholatum.

These results show that CX 9 did, in fact, cause average viewers to believe that the product being described contains aspirin. Specifically, the difference in the response percentages between Aspercreme, on

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[illegible] No information is contained in the record explaining why the percentage of respondents who identified Salycin as the active ingredient in Aspercreme varied so dramatically between the FRC and Lieberman studies. Although the wording of the unaided recall question (Q1) was changed between the two surveys to decrease the percentage of participants who responded "Aspercreme" (Warwick, Tr. 5325), there is no reason to expect that this change would influence the percentage of "Salycin" responses. We would expect that the change in wording in question 1 between the FRC and Lieberman studies would reduce the percentages of participants giving the response "Aspercreme" from 20 to close to 0 percent and cause a corresponding increase in "don't know" responses from 23 to 43 percent. What we find is that the Lieberman study obtained roughly the [illegible] expected Aspercreme responses, i.e., from 20 to 2 percent, 20 percent more "don't know" responses and [illegible] percent [illegible] Salycin responses than expected based on the FRC results.

the one hand, and Ben-Gay and Mentholatum, on the other, allows us to conclude with reasonable [39] confidence that the results of the FRC Test were not caused by survey bias. The questions about the content of Ben-Gay and Mentholatum acted as controls for the survey, and permitted an estimate of the "noise level" generated by various possible random factors, such as confusion on the part of consumers being surveyed or "yeasaying bias" in response to aided questions.[30] The significant difference between the percentage of consumers who thought Aspercreme contains aspirin and those who thought it was contained in the other rubs clearly supports the conclusion that CX 9 generated a net impression of aspirin content among its viewers.[31] [40]

(b) *The ASI Theater Test (CX 27)*

The effectiveness of the disclosure in CX 9 that aspirin is not an ingredient in Aspercreme was also examined in the ASI Theater Test (CX 27) sponsored by complaint counsel. The methodology involved recruiting two groups of subjects to a theater for the ostensible purpose of evaluating a pilot television show. Each group of subjects was shown the same "pilot" show, a standard control commercial for Papermate Flair pens and one of two topical analgesic commercials, *i.e.*, one for Aspercreme and one for Mobisyl (CX 27–E). The next day as many viewers as could be contacted were telephoned and asked unaided and aided recall questions about the products advertised in the theater test and the ingredients they might contain (CX 27–E-H).

It is likely that the responses to the ASI Theater Test show a bias toward relatively increased estimates of the confusion about the information contained in CX 9. This is due to the fact that CX 9 was shown only once, that it was shown along with programmatic material and another commercial, and that participants were not asked questions about the ingredients in these topical analgesics until the next day. Thus, it is likely that the ASI Theater Test resulted in an inflated

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[30] If roughly no more respondents had answered that Aspercreme contains aspirin than answered that Ben-Gay or Mentholatum did, we would conclude that the consumer evidence did not show CX 9 to give a net impression of aspirin content. However, three times as many respondents perceived Aspercreme to contain aspirin even after viewing a disclaimer to the contrary, than perceived that aspirin was an ingredient in Ben-Gay or Mentholatum.

[31] Dr. Warwick, the expert who originally designed the FRC Test for Thompson, argued that it was flawed by its use of aided recall questions and that this is the reason why he designed a second test omitting them. However, we agree with the ALJ's observations (IDF 108) as to why the second study, the Lieberman Test, omitted the aided recall questions found in the earlier study:

> Although Dr. Warwick testified that this was an improvement over the FRC Test design, which he characterized as "flawed," the evidence is also consistent with the conclusion that the direct ingredient question was dropped because it had produced results unfavorable to Thompson in the FRC Test.

Dr. Warwick's testimony to the contrary is unpersuasive in light of the fact that the aided recall questions are widely used in advertising research and the fact that there are numerous ways of reducing the yeasaying bias Dr. Warwick argued such questions can create. For example, one can use controls as Dr. Warwick himself had done in the FRC Test.

estimate of the percentage of respondents who, as a result of CX 9, believe aspirin is an ingredient in Aspercreme (or conversely, a deflated estimate of the effect of the affirmative disclosure that Aspercreme does not contain aspirin). The results from the unaided and aided recall questions contained in the ASI Theater Test are shown in Table 3 below: [41]

Table 3
Percentages of Participants Who Though Ingredients
Were Contained in Aspercreme and Mobisyl

Unaided Recall Mentions of Ingredients in Each Product:*

	Aspercreme Commercial Viewers:	Mobisyl Commercial Viewers:
Aspirin	17%	1%
Salycin	4	0
All other ingreds.	2	5
"No aspirin"	5	0
"None"	4	8
Don't know	66	87
No answer	2	0
(Number of Participants)	(130)	(100)

*The unaided recall question was, "Now thinking about the Aspercreme commercial, as best you can recall, what ingredient or ingredients, if any did the commercial say Aspercreme contained?", followed by the probe, "Were there any other ingredients mentioned in the commercial for Aspercreme?" (CX 27–Z115)

Percentages of Respondents to Aided Recall Agreeing That Various Ingredients Were Contained in These Products:**

	Aspercreme Commercial Viewers:	Mobisyl Commercial Viewers:
Aspirin	38%	5%
Salycin	20	12
Hydrocortisone	32	34
Lanolin	23	22
Menthol	15	19
(Number of Participants)	(130)	(110)

**The aided recall question was, "I'm going to read you a list of ingredients. As I read each one, please tell me if the commercial indicated whether *that particular* ingredient is present in the product even if you mentioned it to me before." (CX 27–Z115) [42]

The results of the aided recall questions are consistent with the hypothesis that a yeasaying bias exists, because a relatively large percentage of participants indicated that the control ingredients hydrocortisone, lanolin and menthol were ingredients in both Aspercreme and the control product, Mobisyl. Nonetheless, the unaided recall results indicate that a sizable percentage of participants did not perceive or remember the disclosure that Aspercreme does not contain aspirin and that a much larger percentage of participants associated aspirin than salycin with Aspercreme. Similarly, the aided recall results indicate that a much larger percentage of those who viewed CX 9 believed Aspercreme contains aspirin than do those who saw the Mobisyl commercial. In addition, despite the likelihood of yeasaying bias which appears to exist in the ASI Theater Test data, the overall results indicate that the net impression conveyed by CX 9 to at least one group of average listeners was that Aspercreme contains aspirin.

(6) What "aspirin" means to reasonable consumers.

In our above discussion, we found that most of Thompson's advertisements have implied representations that Aspercreme contains aspirin. As we noted to begin with, however, one argument Thompson put forward for the proposition that such representations are not deceptive is that consumers understand "aspirin" as a generic description for products that are pain relievers, not only products containing acetylsalicylic acid. Thompson's argument raises the question of whether ordinary or [43] average consumers would interpret the word "aspirin" to imply a specific ingredient or whether they only net impression they would receive would be that of a generic pain reliever, leaving only an unrepresentative subset of consumers to think of aspirin as a specific drug.

The ALJ's initial opinion did not specifically address this point, perhaps because Thompson did not raise it before him with any great degree of clarity (*See, e.g.*, RMF 121, RAB 5). Thompson's argument as we interpret it is that consumers consider "aspirin" to be a generic reference to analgesics, so that representations that Aspercreme contains aspirin do not refer to acetylsalicylic acid. To support the allegations in Paragraphs 10(a), 11(a), 16 and 17 of the complaint—which allege that Thompson falsely represented Aspercreme to contain aspirin—Thompson's argument suggests complaint counsel must show that the product does not contain an effective analgesic.[32]

The controlling question presented by this argument is what reasonable consumers understand "aspirin" to be. It is insufficent for these purposes to note simply that scientists and medical experts understand "aspirin" to mean acetylsalicylic acid, since average con-

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[32] [illegible]

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sumers might not understand "aspirin" as would a scientist or doctor.[33] The conflicting expert opinions [44] offered by the parties on this question, drawing on research designed for other purposes, provide little assistance.[34] [45]

There are, however, three reasons why we are willing to conclude that at least some consumers within the mainstream do not consider "aspirin" to be a generic reference to all types of pain reliever. In the first place, Thompson's own ads repeatedly distinguish between Aspercreme and aspirin. Indeed, several specifically state that Aspercreme does *not* contain aspirin, or that it contains salycin. Thus, the evidence from Thompson's own advertising indicates that asirin is not a generic reference to all analgesics. Second, for aid in interpreting the common meanings of a word we occasionally look to dictionary definitions. They are derived from the ordinary usage of words and, as such, are of some use to us as indication of how [46] reasonable consumers would understand these words.[35] In this case, we have examined two widely used dictionaries, both of which define "aspirin" either as acetylsalicylic acid or as aspirin tablets. Neither of the dictionaries defines it as a generic reference to pain killers.[36] In the third place, we note the extensive advertising contemporaneously with Aspercreme of analgesics whose active ingredient is something other than aspirin, *e.g.*, acetaminophen (CX 54-Z042 to Z047). If there ever was a time when the only analgesics being marketed had aspirin as [47] their active ingredient, so that reasonable consumers might only think of "aspirin" as synonymous with pain killer, that time appears to us to be long past.

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[33] [illegible]

[34] [illegible]

[35] [illegible]

We recognize that consumers today might not be aware that aspirin's proper chemical name is, in fact, "acetylsalicylic acid." Nor do we exclude the possibility that reasonable consumers interpret the word "aspirin" in more than one way, with some thinking of it as a generic pain killer in the manner suggested by Thompson. Indeed, some consumers probably both are unaware of aspirin's chemical name and think of it as a generic pain killer. What we conclude, however, is that those persons who viewed or read the Asprecreme commercials and interpreted them to mean the product contains "aspirin," and who further thought "aspirin" is a specific chemical, fall within the range of persons who would be average or ordinary members of the adult population and, as such, are reasonable consumers. We therefore conclude that one net impression conveyed by Thompson's commercials is that Aspercreme contains acetylated salicylate.

3. *Recent Development of Aspercreme—Paragraph 10(b)*

The ALJ found that Thompson has represented Aspercreme to be a newly discovered or developed drug product (IDF 126, ID 135–36). Thompson has not argued on appeal that this finding was in error. [48]

We agree with the ALJ that the claims were made, but view them as implied rather than express. The representation that Aspercreme is a new product is contained in the headlines of five print ads, CXs 6–8, 10–11. Four of those ads, CXs 6–7, 10–11, contain identical language: "At last! A remarkable breakthrough for arthritis pain: Aspercreme." The headline of the other ad, CX 8, states: "There's always been aspirin . . . Now there's Aspercreme." Both headlines create an implied representation that Aspercreme is a new product by use of phrases that suggest Aspercreme was not hitherto available for purchase. The logical inference is that it was unavailable for purchase because it did not exist. Because the language used in the headlines clearly conveys a message of newness, and because there are no other elements in the ads which might alter the net impression created by the headlines, we find that the implied claims were made. [49]

4. *Aspercreme Is More Effective Than Aspirin Tablets—Paragraph 12(c)*

The ALJ found all of the nationally distributed Aspercreme ads to represent that Aspercreme is more effective than aspirin tablets because it works faster than aspirin tablets, or works without aspirin's side effects such as upset stomachs, or both (IDF 133). Thompson has asserted on appeal that its advertisements contained no such comparative superiority claims (RAB 5, 33).

Our own review of the record leads us to agree with the ALJ that seven of the ads, CXs 1–4, 7–8, and 37, made superiority claims. However, we conclude that there is inadequate information on the record from which to determine whether the remaining ads cited by the ALJ, CXs 5–6, 10–11, and 21–22, would be understood by ordinary consumers to state that Aspercreme is more effective than aspirin tablets.

The seven ads that we find to make comparative efficacy claims do so expressly. They contain either or both of two different superiority claims: (1) Aspercreme provides faster relief than aspirin tablets; and (2) Aspercreme does not cause the side effects of aspirin tablets.

One ad, the print ad CX 8, makes both claims. The headline of CX 8 states that Aspercreme "Works faster, safer than aspirin—relieves pain in minutes." [50]

Three other ads, the TV ads CXs 1 and 3 and the print ad CX 37, claim that Aspercreme lacks the side effects of aspirin tablets. In CXs 1 and 3, an announcer tells viewers that Aspercreme has ". . . none of aspirin's possible side effects." In CX 37, the text of the ad states that Aspercreme "has a *non*-aspirin pain reliever, so it can't cause aspirin's stomach upset or any of aspirin's side effects."

In yet another three ads, the TV ads CXs 2 and 4 and the print ad CX 7, the claim is made that Aspercreme works more quickly than aspirin tablets. In CXs 2 and 4, it is made expressly by a combination of visual and audio elements. As an announcer states "When you take regular aspirin, it goes throughout your body like this," the visual portion of the ads show the outline of a man's body with a few rays

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[illegible] car home for just two thousand five hundred bananas.") However, we will consider dictionary definitions [illegible] indicators of a word's meaning unless other contrary evidence or our own examination of the advertisements [illegible] no reason to think that the context of a word makes dictionary definitions inapposite. It appears that "aspirin" is being used in CXs 3 and 4 in an ordinary manner. Therefore, reference to definitions to learn how consumers might interpret the word appears appropriate.

[36] Webster's Third New International Dictionary 130 (1976) defines "aspirin" as follows:

> 1. a white crystalline compound $CH_3COOC_6H_4COOH$ of salicylic acid used esp. in tablet form as an antipyretic and analgesic like the salicylates but producing fewer undesirable effects—called also acetylsalicylic acid 2. a tablet of aspirin.

A Supplement to the Oxford English Dictionary, Volume I 135 (1972) describes "aspirin" in this manner:

> A white crystalline compound, acetylsalicylic acid, used esp. as an analgesic and antipyretic; with *an* and *pl.*, a dose of this in tablet form. Also attrib.

streaming outward from the stomach. One of these rays is shown reaching the man's left shoulder. The announcer then continues, "But, in seconds, Aspercreme starts concentrating all the temporary relief of two aspirin directly at the point of minor arthritis pain" while the video portion of the ad shows a heavy concentration of rays streaming outward from a point on the left shoulder to the rest of the shoulder. Given the announcer's claim that the outlines compare the ability of Aspercreme and aspirin to provide relief, the fact that the visual images show Aspercreme providing more rays to the shoulder area than aspirin tablets at the same point of time makes an explicit message that Aspercreme provides relief to the area of arthritis pain more quickly than aspirin tablets. In the print ad, CX 7, the text states that Aspercreme [51] "is actually faster and more effective than aspirin in relieving minor arthritis pain." It also states that Aspercreme "works faster than aspirin because you rub it in right where you hurt."

The remaining ads, CXs 5-6, 9-11, and 21-22, contain no explicit comparisons between Aspercreme and aspirin. Instead, they only make statements about the attributes of Aspercreme itself, without contrasting these attributes and those of aspirin. The ads state that Aspercreme does not upset the stomach (CXs 9 and 21-22), or that it has "no side effects" (CXs 10-11), or both (CX 6). None of the ads expressly states that aspirin tablets do upset the stomach or that they have unspecified side effects.

It may be that some consumers think of aspirin in association with stomach upset and that, upon hearing in an ad that Aspercreme does *not* cause stomach upset or other side effects, they would connect the two thoughts and conclude that the ad implies that Aspercreme is superior to aspirin. However, it is equally plausible that consumers would not make this connection. A simple examination of the ads does not provide us with sufficient information to determine whether reasonable consumers come away from these ads with the impression complaint counsel suggest. Therefore, this is a situation where we require extrinsic evidence before we can conclude with confidence that the ads imply Aspercreme is superior to aspirin.

Having examined the record, we do not find sufficient probative evidence to support complaint counsel's position that the ads make superiority claims. The evidence cited in the [52] initial decision (IDFs 134-37) was the opinion of marketing experts to the effect that various Aspercreme ads state the product to be more effective than aspirin. Having looked at the testimony ourselves, however, we note that it was not in reference to CXs 5-6, 9-11, or 21-22. Rather, it referred to those Aspercreme ads that we already have found to make express superiority claims. Therefore, we conclude that the record is insufficient for us to find that CXs 5-6, 9-11, and 21-22 make an implied representation of greater efficacy for Aspercreme than aspirin.

5. *Thompson Had Substantiation for Its Claims That Aspercreme Is Effective—Paragraphs 10c, 14*

The Commission requires that advertisements containing objective product claims be supported by a reasonable basis.[37] If the advertisements contain express representations regarding a particular level of support that the advertiser has for the product claim (*e.g.*, "tests prove") or when the ad implies to [53] reasonable consumers that the firm has a certain level of support, the Commission expects the firm to have that level of substantiation. If the ad does not expressly or impliedly refer to a particular level of substantiation, the Commission determines the adequacy of the advertiser's existing substantiation using a number of factors—such as the ease of obtaining substantiation or the cost of a false claim—identified in *Pfizer, Inc.*, 81 F.T.C. 23 (1972) and subsequent cases.[38]

The complaint in this matter charges Thompson both with representing that it had a particular level of substantiation for claims that Aspercreme is effective (Paragraph 10c) and with making objective product claims (the efficacy claims) that imply the existence of substantiation without representing a particular level for it (Paragraph 14). We conclude that Thompson did make both types of representation. In our discussion, we first will explain why we conclude that several Aspercreme ads represented the existence of a particular level of substantiation. Then we identify, for the remaining ads, the objective product claims implying the existence of a reasonable basis. [54]

The ALJ concluded that two Aspercreme ads, CXs 7-8, represent that valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of minor pain of arthritis and rheumatic conditions (IDF 129). We agree with the ALJ concerning CXs 7-8, and further find that another print ad, CX 37, also represents that efficacy claims for Aspercreme have been scientifically proven. Moreover, we find the claims in all three ads to have been expressly made.

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[37] *For example*, in three other recent analgesic cases we have required that efficacy claims be supported by a reasonable basis. *See Bristol-Myers Co.*, *supra* note 6; *Sterling Drug, Inc.*, 102 F.T.C. 395 (1983), *aff'd*, No. 83-7700 (9th Cir. August 28, 1984); *American Home Products Corp.*, 98 F.T.C. 136 (1981), *aff'd*, 695 F.2d 681 (3rd Cir. 1982). We discuss the operation of our reasonable basis requirement in more detail in Part IV of this decision. However, we note here that the rationale for it under a deception theory is that objective product claims carry with them an express or implied statement that the advertiser has some amount of support for the claim. Consumers find these representations of support to be important information in evaluating the reliability of the product claims. Therefore, injury is likely if the advertiser lacks support for the claims.

[38] *Pfizer* used an unfairness analysis to reach the conclusion that the failure to have a reasonable basis violates Section 5(a) of the FTC Act. We do not rely upon such an analysis here. Rather, we find Thompson's failure to have a reasonable basis is deceptive by using the analysis first used in *National Dynamics* [illegible] F.T.C. 488 (1973), *aff'd and remanded on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974), *reissued*, 85 F.T.C. 391 (1976).

Two of the ads, CXs 7–8, use similar language. Both state that Aspercreme was "tested" by a leading arthritis specialist on his own patients, with the results indicating that Aspercreme is actually faster and better than aspirin. CX 8 additionally refers to the test as a "controlled clinical test." The references to tests by a medical specialist, or "clinical tests," are an express reference to the type of test acceptable to the medical scientific community. Because the ads contain these express claims, we find it reasonable for consumers to expect that the claims that Aspercreme is faster and more effective than aspirin would be substantiated in a manner acceptable to the [55] medical scientific community.[39] The third ad, CX 37, does not compare Aspercreme's effectiveness to that of aspirin, but does expressly claim that Aspercreme's active pain reliver "is clinically proven to give strong, effective relief at the point of arthritis pain." Therefore, we operate on a presumption, which may be rebutted by extrinsic evidence (but was not in this proceeding), that reasonable consumers would expect scientifically acceptable evidence to support the claim that Aspercreme provides effective relief.

Because the representations that scientific substantiation exists are express, we need not consider whether the product claims for which the substantiation supposedly exists are objectively verifiable ones. If an advertiser states that he has substantiation of a given sort for assertions about his product's characteristics, we presume reasonable consumers would believe the substantiation capable of having been acquired by the advertiser. [56]

Having identified three Aspercreme ads that expressly represent the existence of a particular level of substantiation, we next examine whether any additional advertisements contain implied representations that Thompson had a particular level of substantiation for its Aspercreme efficacy claims. We conclude that the record is insufficient for us to find that any do.

Most of the remaining Aspercreme advertisements contain no elements whatsoever that might give reasonable consumers a net impression about a particular level of substantiation. However, four of the ads, CXs 2–4 and 6, contain visual elements that might create in the minds of reasonable consumers a net impression that Thompson was claiming to have scientific or medical substantiation for Aspercreme's efficacy claims. These visual elements are models that some consumers might consider scientific looking (CXs 2 and 4) or line drawings of the human body that also might carry with them a scientific aura (CX 6).[40] Consumers might further draw from such elements, at least where used in drug advertising, the inference that Thompson had performed tests acceptable to the scientific and medical community. On the other hand, it might be that ordinary persons viewing the ads would think no further than that the models and drawings were visual aids to assist the announcer in making points. Because we are unable to interpret these visual elements [57] as implied claims of scientific support and in the absence of extrinsic evidence to assist us in understanding how consumers actually understand these ads, we cannot say whether or not one net impression the ads leave is of the fact that there is scientific support for the assertions that Aspercreme is an effective pain reliever.[41]

Given our conclusion that only three Aspercreme ads expressly represent the existence of a particular level of substantiation and given our further conclusion that the record does not demonstrate any other Aspercreme ads to make such a [58] representation impliedly, we finally must consider whether the efficacy claims in the remaining Aspercreme ads are objective product claims impliedly representing an unspecified level of substantiation, or whether they are "puffing" representations that do not.[42] The issue is not a difficult one to decide. The record in this proceeding contains ample evidence that efficacy claims for OTC pain relievers can be and are objectively verified (*See, e.g.*, CXs 268–69). Indeed, Thompson did not argue that its efficacy claims were puffery, but rather that it had adequate substantiation for them (RAB 9–23). We therefore conclude that all ef-

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[39] On appeal, Thompson has argued that Commission consideration of the fact that CXs 7 and 8 refer to a scientific test as the basis for efficacy claims should be influenced by the fact that "these two print advertisements were disseminated to such a limited extent as to have had virtually no impact in the marketplace" and because the claims were "not prominent" in the body copy of the advertisements (RRB 18). We reject both these contentions. In the first place, our inspection of the ads shows us that the claims Thompson characterizes as being "not prominent" were no more or less prominent than other claims in the body of CXs 7 and 8. In the second place, we reject as fundamentally erroneous the implicit suggestion that an advertiser may avoid responsibility for express representations by later claiming that the representations were not widely distributed. Such arguments may have some bearing on the extent of the relief ordered by the Commission. They have no bearing on the issue of liability for deceptive acts or practices.

[40] These sorts of visual elements also are found in CXs 7–8 and 37, ads which we have already found to represent expressly through other elements contained in them that Thompson had scientific evidence to support its efficacy claims for Aspercreme.

[41] Our approach here is consistent with that we followed in our two other recent analgesic cases, *Bristol-Myers* and *Sterling Drug*, where we concluded that similar visual images were insufficient to show an implied claim of scientific proof. For example, we stated in *Bristol-Myers*, *supra* note 6, at 323:

> [I]n CX 61, 63 and 64, a computer typewriter prints out a column made up of the words "Bufferin" and "aspirin" on graph paper at the same time as the announcer speaks about scientific tests. * * * Although the computer typewriter enhances the implication [of scientific support created by phrases such as "scientific tests show"], . . . we do not think that it alone can create the impression of scientific support for the claim. Similarly, we do not think that glass models of people with Bufferin and aspirin tablets crumbling in their stomachs and reforming in their heads indicates that Bufferin's superior speed has been scientifically established.

The difference between our opinions here and in *Bristol-Myers*, one of emphasis, is due to a refinement in our analysis since we decided that case. There we concluded the visual elements did not convey an impression of scientific support. Here we merely say that complaint counsel failed to provide extrinsic evidence demonstrating that they created a net impression which did. We do not attempt to use our judgment to reach any substantive conclusion. Where the implied meanings of an advertisement are unclear absent extrinsic evidence, our expertise is no more reliable in permitting conclusions that an interpretation is unreasonable than that it is reasonable.

[42] "[T]here is a category of advertising themes, in the nature of puffing or other hyperbole, which do [not] amount to the type of affirmative product claims for which either the Commission or the consumer [illegible] documentation." *Pfizer*, *supra* p. 51, at 64.

ficacy claims in the Aspercreme ads are objective product claims.[43]

III. WERE THE CLAIMS MATERIAL?

After having determined which claims were made by Thompson's advertisements, we next turn to examine whether or not those claims were material. A "material" misrepresentation or practice is one that is likely to affect a consumer's choice of or conduct regarding a product. In other words, it is information that is important to consumers. [59]

The Commission considers certain categories of information presumptively material. First, the Commission presumes that express claims are material. Similarly, when evidence exists showing that a seller deliberately made an implied claim, the Commission presumes materiality. The underlying rationale in both instances is the assumption that the willingness of a business to promote its products reflects a belief that the consumers are interested in the advertising.

In this case, Thompson itself has acknowledged making claims about Aspercreme's basic efficacy in relieving the pain and other symptoms associated with minor pain of arthritis and rheumatism.[44] Because this acknowledgement clearly demonstrates Thompson's intent, we presume that all basic efficacy claims for Aspercreme, whether express or implied, are material. We also have found that several Aspercreme ads expressly represent Aspercreme to be more effective than aspirin tablets and that [60] another set of ads expressly represents Aspercreme's efficacy to have been proven by the results of scientific tests. Therefore, we presume these claims are material.[45]

However, the two remaining claims at issue in this proceeding are implied claims that Thompson has not acknowledged deliberately making. These are the claims that Aspercreme contains aspirin and that it is a new product. In assessing the materiality of such implied claims, we are required to make our own evaluation of whether or not reasonable consumers would consider the information in the claims important. One aid to us in doing so for many claims is the fact that over the years our cases have established several categories of claims pertaining to the central characteristics of a product or service, such

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[43] *See* our discussion of efficacy claims below, at pp. 78-80.

[44] By "basic efficacy claims," we refer to the claims listed in Paragraphs 12a-12c and 12e of the complaint.

[45] In considering the materiality of claims, we are mindful of the Supreme Court's observation in *F.T.C. v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965), that the Commission's inference of materiality must be "within the bounds of reason." Accordingly, we do not use our presumption as an inflexible rule that eliminates our need to [illegible] at materiality on a case-by-case basis. On the contrary, the presumption simply reflects our general judgment that substantive claims in advertisements (in other words, claims other than "puffery" or window-dressing) would not have been made except to affect a consumer's choice or conduct regarding a product. Thus, the very existence of the claim ordinarily is sufficient evidence for us to conclude it is material. However, respondent is always free to counter this evidence either with arguments pertaining to the content of the ad itself or with extrinsic evidence. Moreover, the presumption does not preclude us from exercising our own judgment and concluding from evidence in the advertisement (or extrinsic evidence) that a claim is not material even if the respondent does not dispute materiality.

as those relating to its purpose, safety, efficacy, or cost. We now presume that any implied claim in one of these categories is material. [61]

However, neither the claim that Aspercreme contains aspirin nor the claim that it is a new product appears to fall into any of the above-mentioned categories of claims. Therefore, we must look at the facts on the record to determine whether or not reasonable consumers would consider the claims important.

The ALJ already has analyzed the materiality of the claim that Aspercreme contains aspirin (IDFs 162-64).[46] He found that consumer research in the record shows a significant portion of test subjects preferred an aspirin product over a non-aspirin product for pain relief (IDF 163). For example, in the Lieberman Study 53% of the arthritics tested expressed a preference for an aspirin product (RX 500F, Warwick, Tr. 5333-34).[47] The ALJ also found that Thompson's expert witnesses did not dispute the proposition that aspirin is a drug of choice for treatment of minor arthritic pain (IDF 162). Having reviewed the ALJ's findings, we agree with them and consider them a sufficient basis for concluding aspirin content claims to be material. [62]

The ALJ did not, however, explicitly discuss why claims that Aspercreme is a new product are material.[48] Accordingly, we must examine that issue ourselves.

We conclude that these newness claims are material because they imply product efficacy to arthritis sufferers. Rheumatoid arthritis and osteoarthritis are chronic diseases having no cure (O'Brien, Tr. 3946-47). Arthritis diseases cause suffering to their victims and cripple tremendous numbers of persons each year (CX 268, p. 35,455). As a result, arthritis sufferers are constantly looking for cures, with more money being spent on unproven arthritis remedies than on legitimate arthritis research (Roth, Tr. 1537). Testimony by arthritis specialists (Roth, Tr. 1540; Ehrlich, Tr. 4109-11) and medical literature cited in the record (*See, e.g.*, O'Brien, Tr. 3775-76) show that in this context, where no existing remedy is fully adequate, arthritis sufferers enthusiastically try new remedies in the hope that these remedies will provide relief beyond that they are obtaining from existing remedies.

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[46] The aspirin content claim is the only one whose materiality the ALJ discussed. Because a finding as to materiality is integral to a determination that a representation is deceptive, such findings should be made with respect to any claim upon which a respondent is found liable for deceptive advertising.

[47] By citing to a specific percentage figure (which happens to be over the fifty percent level), we do not mean to imply that any particular level of expressed preference must be reached before we [illegible] conclude a claim like this one to be material. A lower level than that found in this case clearly could also [illegible], depending upon the circumstances surrounding the claim and the intensity of the preference expressed [illegible].

[48] We presume from the general tenor of the ALJ's discussion of this claim (IDFs [illegible]) that he [illegible] in fact believe newness claims to be material.

These facts warrant the conclusion that the Aspercreme ads representing the product as "new," CXs 6–8 and 10–11, also impliedly represent it as a product effective in providing relief of arthritis pain. Efficacy claims are one category of claims [63] that our previous cases have found to concern central product characteristics.[49] Therefore, efficacy claims are presumptively material.

Evidence from the ads themselves confirms our conclusion that Thompson was making implied efficacy representations when it represented Aspercreme to be a new product. Four of the ads, CXs 6–7 and 10–11, use the words "remarkable breakthrough" in describing the product. The headlines in the four ads state: "At last! A *remarkable breakthrough* for arthritis pain: Aspercreme" (emphasis added). A "breakthrough" is something new in the sense that it did not exist for more than a short time before. But it is more than that. A breakthrough is something resulting from a significant advance in scientific knowledge. Use of the word "remarkable" to modify the word "breakthrough" makes even stronger the implied message that the product is the result of a major scientific advance. The net impression left with reasonable consumers may be not merely that Aspercreme, like other products, is an effective arthritis remedy, but that it is a more effective arthritis remedy than the others. However, we find that the newness claims constituted, at a minimum, implied representations of basic efficacy. [64]

IV. WERE THE REPRESENTATIONS ONES LIKELY TO MISLEAD CONSUMERS ACTING REASONABLY?

1. *Factually Inaccurate Claims, Generally.*

To this point, our analysis has shown that Thompson made a variety of express and implied claims that were material to reasonable consumers. However, material claims are not deceptive if the messages they convey to reasonable consumers are accurate. Thus, to make a case that advertising is deceptive, the Commission has the burden of showing that the material claims communicated to reasonable consumers by the advertising are false in some manner.[50] In other words, deceptive representations must be "likely to mislead."[51]

There are two different analytic routes by which complaint counsel can prove advertisments are likely to mislead. One is to carry the burden of proving that the express or implied message conveyed by the ad is false. The other is to show that the advertiser lacked a reasonable basis for asserting that the [65] message was true.[52] For example, if an advertisement claims that a new brand of orange juice is more nutritious than others on the market, the Commission could put on its own evidence showing the claim to be false or it could show that the substantiation the advertiser had to support the ad did not provide a reasonable basis for the claim of greater nutritional value. Because the two forms of proof are different, we keep them analytically separate even where a complaint charges, as does this one, both that the advertiser made false claims and that it made claims lacking a reasonable basis.

In this case, Paragraph 11 alleges that three of the claims made by Thompson were "false, misleading, or deceptive." In other words, the complaint signals that complaint counsel must carry the burden of proving the claims to be false. These three claims are: (1) that Aspercreme contains aspirin (Paragraph 10a); (2) that it is a recently discovered or developed drug product (Paragraph 10b); and (3) that valid studies have scientifically proven it to be more effective than aspirin tablets for the relief of the symptoms of arthritis and rheumatic conditions (Paragraph 10c). We therefore are required to determine whether the evidence put on by the Commission shows the claims to be false. [66]

For the claim that Aspercreme contains aspirin, our above discussion has already demonstrated falsity. The active ingredient in "aspirin" is acetylated salicylate, whereas the active ingredient in Aspercreme is TEA/S. The two are not the same. Therefore, the claim that Aspercreme contains aspirin is false.

The second allegedly false claim is that Aspercreme is a recently discovered or developed drug product. The ALJ's disposition of this issue was not explicitly listed by Thompson as a ruling on which the ALJ erred (RAB 5). However, the company did argue on appeal that most consumers generally had no knowledge of TEA/S products prior to 1979, when Aspercreme national advertising commenced, because Aspercreme itself had only been marketed in Ohio and two other OTC drug products containing TEA/S were: (1) more expensive; and (2) sold mainly through physician recommendation (RAB 3). We infer from this that Thompson believes it was legitimate for CXs 6–8 and 10–11 to claim that Aspercreme was a "new" drug product.

The ALJ found that Thompson had made the representations al-

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[49] See, e.g., Bristol-Myers, supra note 6; Sterling Drug, supra note 37; J.B. Williams Co., 68 F.T.C. 481 (1965), aff'd 381 F.2d 884 (6th Cir. 1967).

[50] See, e.g., Bristol-Myers, supra note 6, at 320: "If an ad conveys more than one meaning to reasonable consumers and one of those meanings is false, that ad may be condemned." National Commission on Egg Nutrition v. F.T.C., 570 F.2d 157, 161 n.4 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978)."

[51] Not only representations are capable of being "likely to mislead." Commission precedent also treats as likely to mislead both practices conveying a material false impression and omissions of material information doing the same. This case involves neither such practices nor such omissions. Therefore, the discussion in the text refers solely to representations. However, the analysis applies equally to other forms of deceptive conduct.

[52] This method of proof is only available to the Commission for objective product claims. For such claims, the representation "X is true" carries with it the implied representation that "The claim 'X is true' is supported by a reasonable basis." The Commission proves that the advertising is likely to mislead by proving that it is not supported by a reasonable basis. This does not preclude the possibility that the claim "X is true" is correct, although the possibility typically is an unlikely one.

leged in Paragraph 10b (IDFs 126-28, ID 135), but was persuaded that such claims were not likely to mislead because they were made "during the period when Aspercreme was being nationally advertised for the first time" (ID 136). Despite finding that Thompson's newness claims were not deceptive when made, the ALJ nonetheless included in his proposed order a ban on making any [67] further such claims, stating, "In any event, Thompson should not make new drug claims for Aspercreme in the future" (ID 136). We disagree with the ALJ's analysis, though not with his result.

As we described above, Thompson's advertising described Aspercreme as a recently discovered or developed drug product, thus representing that the product itself or its drug ingredient was new. In contrast, paragraph 11b of the complaint alleges:

> Aspercreme is not a recently discovered or developed drug product; it has been available for purchase since at least 1971 and its active ingredient has been in existence since at least 1954.

Thompson's arguments and the ALJ's decision both appear to focus only on the "new product" aspects of the complaint allegations in discussing the propriety of the company's claims. The record shows that Aspercreme was not marketed nationally prior to 1979 and that it had only limited availability between 1971 and 1979. In light of this evidence, we cannot conclude that the "new product" claims for Aspercreme are false as alleged.

However, we believe that an order provision prohibiting "new drug" claims is appropriate on the basis of a different paragraph, Paragraph 12. Paragraph 12 states that Thompson made express and implied efficacy representations for Aspercreme. As our discussion in Part III of this opinion shows, the newness claims for Aspercreme also were implied efficacy claims. All [68] Thompson's efficacy claims are deceptive for failure to have a reasonable basis.[53] Therefore, we conclude that an order provision barring the newness/efficacy claims is warranted.

The third claim the complaint alleges to be false is the claim that Thompson possessed a particular level of substantiation for its efficacy claims, that level being scientific tests. This claim was made in three of the Aspercreme ads (CXs 7-8 and 37).[54] To prove these claims false, complaint counsel had to establish the standards a test must meet to pass muster in the view of the medical community as support for the types of claims Thompson was making, and then show that Thompson's tests did not meet these standards. This burden was met.

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[53] Our discussion below, at pp. 61-63, explains why we conclude that Thompson lacked a reasonable basis for its efficacy claims.

[54] See our discussion above at pp. 34-35.

Both our discussion below and the ALJ's findings (IDFs 214-42) reach the conclusion that the standard generally adhered to by the medical scientific community for testing the efficacy of a drug is the possession of two well-controlled clinical tests. The ALJ's careful and methodical examination of every test introduced into the record by Thompson (IDFs 246-333) establishes that the tests fall short of this standard. It follows that Thompson's claims to possess one or more tests acceptable to the scientific community were false. [69]

2. *Claims Lacking a Reasonable Basis*

In addition to charging that Thompson made false claims the complaint alleges (in Paragraph 13) that Thompson lacked a reasonable basis for the objective product claims listed in Paragraph 12. These are the various claims that Aspercreme is an effective drug for the relief of arthritis pain.[55] Thompson's admissions or our own findings have established that the company did, in fact, make such claims. Now we must determine what level of substantiation Thompson should have had for them and consider if Thompson did possess such substantiation for the advertisements in question.[56][70]

Starting with *Pfizer*,[57] and *National Dynamics*,[58] our reasonable basis cases have identified several factors that we will weigh in determining the appropriate level of substantiation for objective advertising claims. We recently summarized the factors, as developed by our prior cases, in a policy statement on advertising substantiation. That policy statement is attached to this opinion as an appendix. The factors it summarizes include: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable.[59][71]

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[55] Paragraph 12 itself identifies three different sorts of efficacy claims found in Thompson's ads: (1) claims that Aspercreme is an effective drug; (2) claims that Aspercreme is as effective a drug as aspirin tablets; and (3) claims that Aspercreme is a more effective drug than aspirin tablets. As a legal matter, it might have been possible for Thompson to possess a reasonable basis for only one or two of the three claims, but not for all of them. For example, Thompson might have tests showing that TEA/S is effective, but not tests comparing TEA/S's efficacy to that of aspirin tablets. In this case, however, none of the evidence offered by Thompson was adequate to support any one of the three types of efficacy claims identified in the complaint. Our discussion therefore does not distinguish among them.

[56] The advertisements in question are CXs 1-6, 9-11, and 21-22. We already have found three other Aspercreme ads, CXs 7-8 and 37, to have expressly represented the existence of scientific proof for Aspercreme efficacy claims. Accordingly, the efficacy claims in these ads would have to be supported by scientific proof regardless of whether or not our analysis here concluded such substantiation was necessary for the remaining Aspercreme ads.

[57] *Supra*, p. 53.

[58] *Supra* note 28.

[59] This case is similar to three other recent Commission cases involving OTC analgesics: *American Home Products*, supra note 37, *Sterling Drug*, supra note 37, and *Bristol-Myers*, supra note 8. These cases speak of "establishment claims" for OTC analgesics and state that if a claim is an "establishment claim," it must be substantiated by two well-controlled clinical tests. We do not use the term "establishment claim" here. However, our analysis is consistent with that we employed earlier. "Establishment claims" are claims that the efficacy of a drug has been scientifically proved, i.e., "established." In our three recent cases, we stated that we require such

(footnote cont'd)

Applying those factors here leads us to conclude that Thompson should possess two well-controlled clinical tests to have a reasonable basis for its Aspercreme efficacy claims. The first criterion we consider is the type of product. In this [72] case, the product is a drug whose application is supposed to improve the physical welfare of its users by reducing pain and the other symptoms of minor arthritis. In past cases involving health or safety issues, we have required a relatively high level of substantiation, typically scientific tests.[60]

The second factor we consider is the type of claim. Our past cases have identified at least two types of claims that require a high level of substantiation, such as scientific or engineering tests. One is a claim that refers to specific facts or figures, rather than making generalized descriptions of the product's capabilities.[61] The other is a claim whose truth or falsity would be difficult or impossible for consumers to evaluate by themselves.[62] This case involves the latter, [73]

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claims to be substantiated by evidence sufficient to satisfy the relevant scientific community of the claim's truth. We further stated that the appropriate level of substantiation for other claims would be determined by considering factors such as the harm to consumers if the claim were false. (These are the factors developed in *Pfizer* and subsequent cases.) *See, e.g., Bristol-Myers, supra* note 6, at 321.

Our analysis here does not employ the term "establishment claim" to avoid creating the impression that claims for an advertiser's possession of scientific proof will be treated by us as a unique category of claims. There is no conceptual or practical reason to single out such claims for special treatment. They are but one example of an express or implied claim that an advertiser possesses a particular level of substantiation. Other such claims might include claims that a particular flower's ability to grow in hot, dry weather had been field-tested (we might require that such claims be substantiated by field tests conducted according to recognized horticultural standards) or that surveys show consumers prefer one brand of orange juice to another (we might require that such claims be backed by appropriate survey research).

Considered from a rigorously analytical perspective, none of these claims actually falls within the advertising substantiation principles set forth in *Pfizer* and subsequent cases. *Pfizer* holds that the Commission itself may identify the appropriate level of substantiation for ads that do not expressly or impliedly claim a particular level of substantiation. It also lays out the factors we will consider in setting the appropriate level of substantiation. We do not have to perform such an evaluation where an advertisement itself makes express or implied substantiation claims. We treat such claims like any other representations contained in the ad. We verify that it is reasonable to interpret the ad as making them, that the claims are material, and that they are false. If so, they are deceptive under Section 5(a) of the FTC Act.

Such an analytic approach is easier for us to employ than if we have to evaluate a case using the *Pfizer* factors. However, the end result in either event, assuming we find liability, is an order requiring the advertiser henceforth to have substantiation for the objective product claims being made. From the perspective of the final result, therefore, all cases ending up in a substantiation order can be considered ad substantiation cases.

This case involves both ads expressly claiming a particular level of substantiation and those to which we must apply the factors outlined in *Pfizer*. The express substantiation claims are those in CXs 7-8 and 37, ads representing that scientific tests prove Aspercreme to work faster and more effectively than aspirin tablets. We discussed these claims at pp. 58-60, above. However, the remaining Aspercreme advertisements did not make express or implied claims to a particular level of substantiation. Therefore, in this section of the opinion we employ the *Pfizer* factors to identify the proper level of substantiation for these advertisements.

[60] *See, e.g., Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 475 (1972), *aff'd*, 481 F. 2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973) (safety and performance claims for automobile tires must be substantiated by "competent scientific tests"); *National Commission on Egg Nutrition*, 88 F.T.C. 89, 192 (1976), *aff'd*, 570 F.2d 157 (7th Cir.), *cert. denied* 439 U.S. 821, *reissued* 92 F.T.C. 848 (1978) ("Parties making claims about the attributes of products—and particularly about the safety of products—owe to the public a high degree of precision and care"); *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 865 (1977), *aff'd*, 605 F. 2d 294 (7th Cir. 1979), *cert. denied* 445 U.S. 950 (1980) (claims that any food, drug, or device can help a user achieve any result, such as weight loss, must be substantiated by "competent scientific or medical tests or studies").

[61] *See, e.g., National Dynamics Corp., supra* note 38 (valid laboratory tests would provide reasonable basis for claims concerning specific attributes of battery additive, such as claims for "quick starts in −40 degrees" or "increases brightness of lights by 25%").

[62] *Bristol-Myers, supra* note 6; *Sterling Drug, supra* note 37; *American Home Products, supra* note 37.

not the former type of claim.[63] As the ALJ's opinion explains in some detail (IDFs 196-206), arthritis pain is a phenomenon that is not constant. The pain ebbs and flows, making it hard for individual consumers to assess for themselves whether the relief they feel at a given moment is due to a particular treatment they are taking or is a natural phenomenon. This difficulty would be compounded for a new product such as Aspercreme by the "placebo effect," a phenomenon whereby patients' hopes and expectations cause them to believe, often for extended periods of time, that a clinically ineffective medication is providing them with real relief.[64] (The same placebo effect is also capable of influencing doctors' judgments about drugs they are testing or [74] prescribing if they know a drug's identity.) Thus, efficacy claims for Aspercreme are precisely the sort that consumers would not be able to verify easily for themselves.[65]

We often consider the third and fourth *Pfizer* factors in conjunction with each other. The third factor is the benefit of a truthful claim. The fourth factor is the ease of developing substantiation for the claim. Our concern in analyzing these factors is to ensure that the level of substantiation we require is not likely to prevent consumers from being told potentially valuable information about product characteristics. In this case, the benefit to consumers from the advertising messages in dispute would be significant if Aspercreme provided both faster relief and relief with fewer side effects than aspirin tablets. However, the record in this case does not suggest that requiring two well-controlled clinical tests as substantiation of efficacy claims for this product (or similar analgesics) would significantly reduce the likelihood of consumers being told about effective remedies for the relief of arthritis pain. The market for such remedies is large, being in excess of 18 million persons [75] in the United States alone.[66] The

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[63] Some Aspercreme ads refer to the product as providing relief in "seconds." It could be argued that these ads refer to specific figures for the speed with which the product acts. On balance, however, we do not find these references to be the sort of specific figures (e.g., "provides 30 amps starting power at zero degrees Farenheit") referred to in the cases holding advertisers who make such claims to a higher level of substantiation than otherwise.

[64] Two additional factors noted by the ALJ also would make it difficult for consumers to evaluate the efficacy of Aspercreme in a nonclinical setting. Many consumers use other medications as well as Aspercreme. This would make it hard for them to separate out which product is the source of the relief they feel (IDF 198). Furthermore, the method of applying Aspercreme is by rubbing. Rubbing itself is known to have a soothing effect upon musculoskeletal pain (IDF 199). The relief generated by rubbing might be attributed to a nonexistent medical effect of the product being rubbed, masking the product's ineffectiveness.

[65] The fact that consumers and doctors in uncontrolled environments cannot readily evaluate the efficacy of Aspercreme is a principal reason why we reject Thompson's claims that efficacy of the product can be substantiated by evidence such as the clinical observations of doctors or marketing data (RAB 29).

[66] The report of the FDA Panel on OTC Internal Analgesics (CX 268, p. 35,455) provides the following statistics:

Incidence of rheumatic disease [arthritis] in the United States during 1974

Rheumatic disease	Number of persons
Osteoarthritis	[illegible]
Rheumatoid arthritis	[illegible]
Gout	[illegible]

[illegible]

potential sales for such a remedy are correspondingly large, as is evidenced by the fact that Thompson's 1981 sales of Aspercreme approached $6 million (IDF 74). By comparison, the cost of a well-controlled clinical trial of an analgesic's efficacy would be between $10,000 and $15,000 (Adriani, Tr. 1176–77, Roth, Tr. 1562). This means the total cost of complying with the reasonable basis requirement we establish for Aspercreme would not exceed approximately $30,000. In view of the large potential market and likely high demand for analgesics suitable for treating arthritis symptoms, these costs should not deter the development or advertising of new arthritis remedies.

The fourth factor we consider is the consequences of a false claim. In this connection, the ALJ's opinion stated that use of an ineffective drug (*i.e.*, one not significantly different from a placebo) to treat arthritis would be both injurious to health (IDFs 207–09) and economically harmful to consumers (IDF 210). Having reviewed the evidence, we agree with the ALJ's finding that the failure to treat arthritis with effective remedies can [76] cause significant economic harm to the consumer. These costs result from the repeated purchase of an ineffective product by consumers who are unable to evaluate drug efficacy in an easy manner. However, we differ with the ALJ's findings regarding the health effects of Aspercreme.

The ALJ notes (IDF's 208–09) that failure to diagnose and treat rheumatic diseases with effective medication can seriously harm an individual's health. Where an OTC product is represented or used as a long-term treatment or cure for arthritis, there is a potential for substantial consumer injury because OTC products do not prevent the progression of the two principal forms of arthritis—osteoarthritis and rheumatoid arthritis.[67] Where an OTC product is advertised or used for the temporary relief of minor arthritis pain, in contrast, there is little potential for the product to cause serious injury to consumers' health if [77] claims about its effectiveness in relieving pain prove false. In this case, we find that the health risk from using Aspercreme as represented to relieve minor arthritis pain is uncertain and should

be minimal if the product is used according to the warning on the label that a physician should be consulted if pain persists beyond a short period of time.

The sixth factor we consider is the amount of substantiation experts in the field would consider reasonable. As has been made clear in our past decisions[68] and by the ALJ's initial decision in this matter (IDFs 214–22), the substantiation standard generally applied by the scientific and medical community to claims for the efficacy of an analgesic is that they must be based on the results of at least two well-controlled clinical trials. Evidence from the record of this matter showing that this is the general standard includes the fact that regulations issued by the Food and Drug Administration[69] apply such a standard to all OTC drugs and the fact that the standard was applied to analgesics in particular, by the panels of independent experts who evaluated OTC internal analgesics and external analgesics (including TEA/S) for the FDA (CXs 268 and 269). [78]

The FDA regulations recognize the possibility of exceptions to this general rule.[70] In fact, the panels reviewing OTC external and internal analgesics each approved a few OTC drugs without requiring two clinical tests, as Thompson has pointed out (RAB 14–15). However, the existence of these exceptions is not inconsistent with a general rule in the medical community requiring two well-controlled tests to show efficacy, any more than would be the existence of a minority body of opinion holding to some other standard.[71]

In this case, we have not only evidence of the standards generally applied by the medical community to efficacy claims for OTC drug products, but specific evidence that impartial experts do not believe TEA/S's efficacy to have been demonstrated [79] according to appropriate standards. The "active" ingredient of Aspercreme was reviewed by the Panel on OTC External Analgesics in 1979. It held that the efficacy of TEA/S had not been established (CX 269, p. 69,856). After the panel's report was submitted to the FDA, agency personnel independently evaluated the panel's findings. During FDA's evaluation period, interested persons were entitled to submit additional

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Systemic lupus erythematosus	0.4 to 0.5
Juvenile rheumatoid arthritis	0.25

[67] Our conclusions about potential physical harm to consumers rest in large part upon the characterizations of arthritis provided by the monograph of the FDA's Panel on OTC Internal Analgesics (CX 268). The panel notes that each of the two principal forms of arthritis—osteoarthritis and rheumatoid arthritis—has a different cause, a different prognosis, and a different method of treatment. (CX 268, p. 35483) Active treatment of osteoarthritis requires physical measures and surgical management to retard progression of the disease. As the panel reports, "[n]o medication has been shown to retard the development or progression of degenerative joint disease (osteoarthritis). Pharmacologic agents (drugs) play a relatively minor role in the management of osteoarthritis." (Id., p. 35483) Aspirin is the mainstay of therapy for rheumatoid arthritis, but it must be administered in dosages much higher than those listed on labels of OTC products sold for the relief of pain in order to obtain the anti-inflammatory effects that retard progression of the disease. OTC drugs, including Aspercreme, do not prevent the progression of these common forms of arthritis, and their continued use as sole medication could result in serious health consequences to consumers.

[68] *See, e.g.*, *Bristol-Myers*, *supra* note 8, at 338, 376–77.

[69] 21 C.F.R. 314.111(a), 330.10(a)(4)(ii) (1982).

[70] *See, e.g.*, 21 C.F.R. 330.10(a)(4)(ii):

> . . . Proof of effectiveness shall consist of controlled clinical investigations as defined in §314.111(a)(5)(ii) of this chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered. General recognition of effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

[71] We do not believe it necessary in deciding this case to attempt to identify all the situations when exceptions from the general rule will be permitted. The positions of the Panel on OTC External Analgesics and of the FDA on TEA/S demonstrate that an exception is not appropriate for this particular substance.

evidence supporting the efficacy of ingredients that the panel had found not to be proven effective. Accordingly, Thompson submitted to the FDA the studies it asserts in this proceeding to be well-controlled clinical tests. The results of FDA's deliberative process and its evaluation of Thompson's evidence are found in the "tentative final monograph" on OTC external analgesics, which was published for public comment in 1983. The tentative final monograph reiterates the panel's conclusion that TEA/S has not been proven effective and dismisses each of Thompson's proffered "clinical tests" as inadequate (CX 443, p. 5,855).[72] Although the tentative final monograph is subject to public comment and possible revision before the FDA publishes a final monograph, the tentative final monograph reflects the agency's considered judgment and current position on the merits.

Therefore, based upon our review of the six *Pfizer* factors, we conclude that the proper level of substantiation for Aspercreme efficacy claims is two well-controlled clinical [80] tests. We are additionally persuaded to use this level of substantiation because our above discussion indicates that this is the standard currently being required of TEA/S by the Food and Drug Administration. We believe that advertisers of drug products subject to the joint jurisdiction of the FTC and the FDA will benefit from greater regulatory certainty if they can act with reasonable assurance that the two agencies will accept the same evidence to demonstrate the safety and efficacy of a particular ingredient. Thus, we state that advertisers who comply with the FDA's requirement of well-controlled clinical tests to demonstrate efficacy have adequate substantiation to make such claims in their advertisements. Although we do not preclude ourselves from also permitting advertisers to use other types of evidence to comply with our substantiation requirement, nothing in this record suggests any rationale for our permitting a different form of substantiation for efficacy claims in Aspercreme advertisements than the FDA is prepared to establish for the product's labeling.[73] On the contrary, the inability of consumers to evaluate analgesic effect by themselves in an uncontrolled environment is a persuasive reason for consumers to expect (and us to require) appropriate scientific testing before efficacy claims are made. [81]

In reaching our conclusion that Thompson lacked a reasonable basis for its Aspercreme efficacy claims, we reject Thompson's arguments to the contrary. The first argument, relying on the testimony

at trial of Thompson's expert witnesses, is that the scientific and medical community does not consider just one type of evidence (*i.e.*, well-controlled clinical tests) sufficient to demonstrate drug efficacy (RAB 13). While the argument would be true enough if it were merely an assertion of the point hitherto acknowledged by us, that the medical community may on occasion permit an exception to the general rule of well-controlled clinical tests, this is not what Thompson would have us find. Rather, the company wishes us to accept the proposition that the medical community does not, as a general matter, require well-controlled clinical tests to support claims of drug efficacy. We find this assertion contrary to the preponderance of the evidence in the record of this case and, accordingly, reject it.

Thompson next asserts that not even the FDA requires the existence of two adequate and well-controlled studies as the basis for an OTC drug efficacy claim (RAB 14-16), relying principally on the fact that FDA panels reviewing various OTC drugs have not invariably required such evidence. As we stated earlier, however, the existence of exceptions does not, in and of itself, disprove the existence of the general rule. For example, the three external analgesics approved by the FDA Panel on External Analgesics without two well-controlled clinical tests came from a group of over forty drugs reviewed by that panel (CX [82] 269, p. 69,790). Moreover, complaint counsel have presented us with persuasive explanations of why these particular exceptions were made.[74]

Third, Thompson argues that it did have three double-blind clinical studies on Aspercreme, studies that met the applicable standards of the FDA and the medical community (RAB 17-18). We find it remarkable that Thompson would make this assertion in light of the FDA's present position that Thompson's studies are [83] inadequate (CX 443, p. 5,855). Moreover, we are independently persuaded by the evidence on our own record (discussed in IDFs 246-312) that each of Thompson's tests had one or more serious flaws that prevents it from complying with the standards for a well-controlled clinical test.

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[72] The FDA's position contradicts Thompson's assertion (RAB 17) that "... three double-blind clinical studies support[ ] efficacy [of Aspercreme]."

[73] Consistent with this view, our order would permit Thompson to advertise Aspercreme as an effective analgesic "... if the Food and Drug Administration promulgates any final standard that establishes conditions under which such product is safe and effective under the Food, Drug, and Cosmetic Act," whether or not the standard requires two well-controlled clinicals. (We have no reason to think FDA would dispense with the requirement of two well-controlled clinicals.)

[74] Complaint counsel's answering brief states (CAB 10):

> Two of the drugs Thompson points to are counter-irritants, which are a specific class of drugs that exert their analgesic action in a unique way, by producing the sensation of warmth or coolness on the skin. Accordingly, once these drugs' mechanism of action is understood, clinical trials of various counterirritants would be adequate to document the efficacy of counterirritants as a class (Bush, Tr. 1763-64). Moreover, in the case of all three of these external analgesics, the External Analgesic Panel specifically states that there are reports about each in the published literature and even in authoritative compendia on drugs. In contrast, TEA/S is an obscure drug, and is not listed in any of these compendia. (F. 346) (IDF 346)

Also explanatory of the exceptions are the comments of the Panel on OTC External Analgesics [illegible]. For example, in discussing turpentine oil, one of the two counterirritants it found effective, the panel sta[illegible]

> Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that turpentine oil is effective for use as an OTC external analgesic.
>
> No scientifically controlled studies concerning the use of turpentine oil alone for the treatment of rheumatism, arthritis and muscular aches and pains were found. However, the use of turpentine oil [illegible] is rooted in American folk tradition, and [illegible] a good counterirritant (CX 269, p. [illegible])

Finally, Thompson argues that its possession of a reasonable basis for its Aspercreme ads is underscored by the quality of the individuals who came forward to testify on its behalf (RAB 20–21). Unfortunately for Thompson, however, none of the factors established by *Pfizer* or our other reasonable basis cases suggests that the credentials of a respondent's witnesses should be a substitute for factual evidence as a basis for objective product claims. Moreover, the testimony of experts, no matter how well-qualified they may be, is no substitute for controlled clinical testing as a means of substantiating the drug efficacy claims at issue in this case.

In addition to the above arguments, Thompson asserts that it is inappropriate for the Commission to take action against Aspercreme before the FDA reaches a final decision on whether or not TEA/S has been proven effective (RAB 28–31).[75] In other [84] words, Thompson suggests that it is inappropriate for the Commission to reach a final decision on whether or not TEA/S has been proven effective when the issue is still an open question at the Food and Drug Administration. Thompson further implies that evidence it submitted to the FDA too late for that agency to review prior to publication of the tentative final monograph on OTC external analgesics will persuade the FDA to conclude that TEA/S has been proven effective when it publishes the final monograph on OTC external analgesics.

It is true that the FDA's proceeding is still open and that the agency could reverse its tentative decision on TEA/S. However, we have no reason to believe this will happen. As the ALJ's initial decision points out (IDFs 387–99), the new material submitted by Thompson to the FDA does not appear to contain two (or even one) well-controlled clinical tests. Therefore, if the FDA continues to apply the standards it heretofore has applied to TEA/S, it should not find the new materials any more persuasive than the old.

In any event, our decision to issue an order in this proceeding does not rely upon a guess as to how the Food and Drug Administration ultimately will come out on the question of TEA/S's efficacy. Rather, it is based upon Thompson's failure to provide us with evidence that we think provided a reasonable basis for Aspercreme's efficacy claims. Moreover, the order we issue contains language allowing Thompson to rely for substantiation of Aspercreme efficacy claims

upon any evidence conforming to a final standard for efficacy promulgated by the [85] FDA. Thus, if the FDA changes its position the result amounts to an automatic modification of our order.[76]

Indeed, we see very good reason for us to take action on Aspercreme despite the pendency of the FDA's OTC external analgesics review. FDA's proceeding is a rulemaking that must focus simultaneously on many different drugs, one of which is TEA/S. As Thompson itself has noted (RAB 30), while the date set for close of comments on the FDA's external analgesics tentative final monograph was April 9, 1984, it is uncertain how much additional time FDA will need before resolving all of the issues presented to it by the rulemaking. In contrast, the proceeding before us is an adjudicative one focused specifically on Aspercreme. Perhaps for this reason, we are in a position to reach our final determination before the FDA is able to reach its final determination. Given our conclusion that the Aspercreme advertising in evidence on our record is deceptive for failure to have a reasonable basis (among other reasons), it is in the public interest for us to act expeditiously to prevent further harm from the continuation of such advertising. [86]

V. SCOPE OF RELIEF

This part of the opinion discusses the order we enter against Thompson to prohibit and prevent it from engaging in deceptive acts or practices. Our order differs in several respects from the one proposed by the ALJ. Accordingly, we first discuss the rationale for each of our changes. We then discuss why we believe it appropriate for the order to apply not only to Aspercreme, but also to other drug products marketed by Thompson. Finally, we explain why we decided not to adopt an order provision that was urged upon us by complaint counsel, one that would have required Thompson to excise the "Aspercreme" brand name.

Our first change removes from the first paragraph of Parts I and II the word "labeling." The effect of this deletion is to limit application of the order to the "advertising, offering for sale, sale or distribution" of drug products. Our revision is intended to ensure that the order cannot be interpreted as applicable to any information the Food and Drug Administration either permits or requires Thompson to place on the labels of its drug products. For example, if the FDA permits Thompson to characterize Aspercreme as an analgesic during the pendency of the FDA's OTC drug review process, our order would not bar such labeling. On the other hand, any advertising placed on the label (*i.e.*, language not covered by FDA regulations) would be covered [87] by the order. The order as revised by us is identical with the orders in our three other recent analgesics cases, *American Home Products*, *Bristol-Myers*, and *Sterling Drug* in this respect.

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[75] This is a favorable reading of Thompson's argument. As written, Thompson's brief merely asserts the ALJ [illegible] "erred in holding that the External Analgesic Panel and the FDA have found TEA/S to be ineffective as a topical analgesic ingredient." However, nothing the ALJ stated in the initial decision suggests that he believed the FDA to have made a final determination. He correctly characterized the position expressed in the FDA's tentative final monograph for external analgesics (CX 443) as the FDA's "current position" (IDF 386). He stated his further belief that it is "highly unlikely" the FDA will reverse its position (IDF 400). He never expressly or impliedly stated that the FDA had finally determined TEA/S to be ineffective.

[76] We have included this language in our order because of our aforementioned view that it is advisable [illegible] and the FDA to take a unified regulatory approach to issues brought before us where the issues appear [illegible] or quite similar.

The ALJ apparently added the word "labeling" to Parts I and II to address a concern of complaint counsel. They felt the disclosure mandated by Part I.A (stating Aspercreme does not contain aspirin) had to be made both in Thompson's advertising and on the product label to be effective and that, therefore, the order had to apply to labeling (CPF 487). We agree with complaint counsel's belief that the disclosure needs to be on the product label to be effective. However, Part I.A of our revised order still requires that Aspercreme labels contain the desired disclosure *if* Thompson wishes to continue using the "Aspercreme" brand name in advertising or sales or otherwise to represent in ads that the product contains aspirin. Thus, the net effect of our revision is to make continued advertising and sale of a product named "Aspercreme" conditional upon a disclosure on its label that it does not contain aspirin, but not to make the order applicable to any labeling regulated by the FDA.

Our second change in the ALJ's proposed order broadens coverage of its Part I from "over-the-counter analgesic drugs" to "over-the-counter drugs" generally. We have broadened Part I's coverage because we agree with complaint counsels' argument on appeal that the facts of this case warrant such "fencing-in" to prevent deceptive acts or practices by Thompson in the future. We discuss in more detail below our reasons for reaching this conclusion. [88]

Our third change modifies the language of Part I.A by replacing the last "or" in it with the words "*provided, however*," and by making other conforming changes. We made this technical revision because the langugage approved by the ALJ could literally be read as permitting Thompson to represent expressly (or impliedly) that Aspercreme contains aspirin as long as Thompson's advertising and labeling contained a disclosure that it does not. Our revision makes clear that Thompson may engage in no such conduct (other than use of the brand name "Aspercreme") regardless of whether or not it uses the disclosures required by the order.

Our fourth change is a revision to Part I.A.1 of the order. That provision sets out the requirements for disclosures that Aspercreme does not contain aspirin when the disclosures are used in television advertisements. As approved by the ALJ, it not only specified that the advertisements include both a clear and prominent vocal statement at the end of each ad informing consumers that Aspercreme does not contain aspirin and a clear and prominent video super advising consumers of the same fact, but also specified that the super must be displayed throughout the length of each advertisement. The requirement that the super be perpetually displayed throughout an entire ad strikes us as overkill. We have not imposed a similar requirement in any of our past affirmative disclosure cases and do not believe it is appropriate to do so here. Instead, we have revised Part I.A.1 to require that the visual super be displayed at the end of the ad simultaneously with the vocal disclaimer. [89]

Our fifth change from the ALJ's proposed order revises the language of Part I.B., the provision prohibiting false newness claims. We have made several changes in this provision. First, we have deleted the reference to new "mechanical" principles. Nothing in this case suggests Thompson has claimed (or plausibly could claim) that the efficacy of an OTC drug is based upon new mechanical principles. Second, we have deleted the prohibition on generally representing that a product is new (as opposed to representing that it involves new scientific principles) because the materiality of newness claims in general has not been established by the evidence before us. Third, we have deleted the language excepting from operation of the provision claims of newness made during a product's introductory period. We see no reason why Thompson, or any other advertiser, should be entitled to use the excuse of a "new" product (*e.g.*, an aspirin tablet marketed under a new brand name) to represent directly or indirectly for any period of time that the product is the result of a new scientific principle (*e.g.*, a new active ingredient) when it is not. Finally, to clarify the operation of Part I.B we have replaced the phrase "generally available for purchase" with the phrase "available for purchase as an over-the-counter drug." [90]

Our sixth change replaces a part of the order deleted by the ALJ, one that prohibits Thompson from misrepresenting the active ingredient(s) in any OTC drug products. The ALJ's initial decision does not explain why he omitted this provision, which had been included in the notice order accompanying the complaint. Whatever his rationale, we agree with complaint counsels' argument on appeal that the deletion was incorrect. Part I.D. of our order, the provision deleted by the ALJ, is based on one of the basic deceptive practices this case has shown Thompson willing to engage in—the misrepresentation of active ingredient. It prohibits such misrepresentations for any OTC drug products. Although Part I.A of the order prohibits the specific misrepresentation involved in this proceeding, misrepresentation of aspirin content, we believe Part I.D is necessary as fencing in for the same reasons that prompt us to broaden the coverage of Part I from OTC analgesic drugs to OTC drugs generally. We discuss these reasons below.

Our seventh change is to Part II.A of the order. That part prohibits

Thompson from representing any OTC analgesic drug to be effective for the relief of symptoms of musculoskeletal disorders, unless Thompson has a reasonable basis for such claims, *i.e.*, two well-controlled clinical tests. Our revision removes a "delayed" effective date (April 9, 1984) that no longer would be in the future, given the passage of time since the ALJ issued his initial decision. An alternative would have been to extend the delay until such time as the FDA makes its final determination about TEA/S's efficacy. Unlike the ALJ, however, we question the [91] wisdom of such a course. Thompson already has had ample time during the pendency of this litigation to conduct the sort of tests that could establish efficacy to our satisfaction. If it has not done so, either out of conviction that it is not required to or out of fear that such tests would show Aspercreme to be no better than a placebo,[77] it will have to stop making efficacy claims in its advertising and offering for sale of Aspercreme until those tests are performed. While the inability to advertise that Aspercreme is effective will make it difficult (although not absolutely impossible) to market Aspercreme for a period of time, Thompson can always resume a full-scale selling campaign if and when it obtains the evidence of efficacy that it should have had all along.

Our eighth and final change is to add back to the order Parts IV and V, standard provisions for all our orders. Part IV requires Thompson to notify us prior to any proposed change in the corporation. Part V requires the company to file a compliance report within 60 days after service of the order upon it. These provisions appear to have been inadvertently omitted from the ALJ's proposed order. [92]

The order we adopt contains fencing-in provisions, *i.e.*, it would place restrictions on Thompson's ability to market products other than Aspercreme. Part II of the order requires a reasonable basis consisting of two well-controlled clinical tests if efficacy claims are made not just for Aspercreme, but for any OTC analgesic drug. Part I applies not only to analgesics, but also to any other OTC drug products Thompson might sell. We believe such fencing-in provisions are warranted in this case.

The ability of the Commission to issue orders containing fencing-in requirements is clear. *See, e.g., FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1965). The Commission has wide latitude in fashioning orders to prevent inventive respondents from pursuing a course of conduct similar to that

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[77] [illegible] a fear might well be warranted. As the ALJ's opinion notes (IDFs 376-80) five studies in evidence in this [illegible] find no statistically significant difference between TEA/S and a placebo. The ALJ concluded that these studies, like Thompson's, were not well-controlled (IDF 374). However, the relative quality of these studies versus those relied on by Thompson is suggested by the fact that the FDA's Tentative Final Monograph on OTC External Analgesic Products cited to the findings of four of these studies as evidence that TEA/S has not been proven effective, and did so without critical comment, while criticizing the methodology of Thompson's three supposed clinical tests ([illegible] p. [illegible]).

found to have been unfair or deceptive in the past. However, the Commission's discretion is subject to two constraints. One is that the order must be sufficiently clear and precise to be understood by the violator. *See, e.g., Colgate-Palmolive*, 380 U.S. at 392. The second is that the order must bear a reasonable relationship to the unlawful practice found to exist. *See, e.g., Jacob Siegal Co. v. FTC*, 327 U.S. 608, 612-13 (1946).

To ensure that a multi-product fencing-in order such as this one bears a reasonable relationship to the unlawful practice found to exist, the Commission considers three factors. They are: (1) the deliberateness and seriousness of the present violation; (2) the respondent's past history of violations; and (3) the transferability of the unlawful practices to other [93] products. The more egregious the facts with respect to a particular element, the less important it is that another negative factor be present. *See, e.g., American Home Products Corp. v. FTC*, 695 F.2d 681, 706 (3d Cir. 1982); *Sears Roebuck & Co. v. FTC*, 676 F. 2d 385, 392 (9th Cir. 1982). In considering these three factors, we find that two of them, the deliberateness and seriousness of the present violation and the transferability of the unlawful practices to other products, warrant adoption of the order we enter today.[78]

We look first at Thompson's present violations of the law. We have concluded that they are deliberate and serious. The seriousness of Thompson's violations is evidenced by the size and duration of Thompson's deceptive advertising campaign. As our above discussion shows, Thompson has been making deceptive efficacy and aspirin content claims since it began advertising Aspercreme in 1977. These claims have been made in numerous different ads on TV and in print in a campaign backed up by a multi-million dollar advertising budget (IDF 74). Such a persistent, long-term pattern of deceptive advertising evinces a [94] "massive, long-standing effort"[79] to persuade consumers that Aspercreme contains aspirin and that there is a reasonable basis for claiming it is effective.

The ads claiming that Aspercreme is a new breakthrough and that its efficacy is supported by scientific tests were run only in print ads, rather than in the TV commercials that commanded the bulk of Aspercreme's budget (RX 573). Even so, these ads were not insignifi- [illegible] For example, the CX 6 print ad ran twice in the *Reader's Digest* [illegible]nce in the *Saturday Evening Post* in 1979 (CX 25A). Print ads in such magazines of nationwide distribution would result in the objectionable representations being seen by large numbers of persons.

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[78] Complaint counsel argued on appeal that Thompson's history of past violations also provides grounds for a fencing-in order. However, the history cited by complaint counsel consists of a single consent order against Thompson issued in the early 1960s. *Thompson Medical Company, Inc.*, 59 F.T.C. 287 (1961) (CAP 17-18). Because consent orders do not constitute a legal admission of wrongdoing, we will not use a single consent order as a basis for concluding that Thompson has a history of past violations. We express no opinion on whether or not a pattern of consent orders would be a sufficient history of past violations to warrant fencing-in.

[79] *See American Home Products Corp. v. FTC*, [illegible]

The seriousness of the violations also is affected by the fact that consumers could not readily judge the truth or falsity of the claims Thompson was making.[80] As our discussion above has noted, consumers cannot readily determine on their own whether or not an analgesic is effective. It would be even harder for them to determine whether or not a product advertised as a new "breakthrough" actually is one or to figure out whether supposed scientific tests showing that a product is faster and safer than aspirin would pass muster according to the general standards of the scientific community. Therefore, the claims Thompson emphasized in its advertising were ones to which consumers were particularly susceptible. [96]

Just as troubling as the seriousness of Thompson's violations is their apparent deliberateness. Deliberateness is shown by the consistency of Thompson's advertising themes over the years, supporting a conclusion that they were no accident or "isolated instance." *See, e.g., Jay Norris Inc. v. FTC*, 598 F.2d 1244, 1250 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979).

Thompson has attempted to rebut the notion that it engaged in a deliberate campaign of deception by claiming that it did everything possible to ensure it had a reasonable basis for its Aspercreme efficacy claims.[81] We do not find it so easy to exonerate Thompson's conduct. Thompson excuses itself by asserting that it relied on the opinions of scientists it hired [96] as consultants, who advised it that Aspercreme was effective. Thompson seeks to avoid the charge that it should have realized those scientists were not relying on well-controlled clinical tests by arguing that it does not conduct in-house clinical investigations and lacks the expertise to evaluate such studies itself (RAB 9).

However, the facts on the record in this proceeding show a pattern of outside sources repeatedly warning Thompson that the efficacy of TEA/S had not been established. The FDA's Panel on OTC External Analgesics expressed this view in 1979. In early 1980, the National

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[80] *Id.*

[81] *See, e.g.*, Respondent's Answering Brief, at 7:

> The record shows that the state of mind of Thompson, from the time it first purchased the product Aspercreme (and even before), was directed towards satisfying itself, and accumulating ample scientific proof, that Aspercreme was both safe and effective for the temporary relief of minor musculoskeletal pain, including that minor pain associated with arthritis and rheumatism. Towards this goal, Thompson accumulated, at great expense, extensive medical and scientific opinions, reports and clinical documentation from numerous outstanding, well recognized authorities and experts.

Thompson also argues that its [illegible] money-back guarantee evidences its good faith reliance on the evidence that Aspercreme is effective. *Id.* at 10. However, a money-back guarantee is not a defense to a charge of deceptive advertising. *See, e.g., Montgomery Ward & Co. v. FTC*, 379 F.2d 666, 672 (7th Cir. 1967). In this case, the placebo effect would result in some consumers purchasing the product many times before discontinuing its use and/or asking for a refund on the last bottle bought. Therefore, a money back guarantee would not eliminate substantial sales revenues even in the unlikely event that all consumers eventually invoked it.

Association of Broadcasters and each of the television networks advised Thompson that the documentation for Aspercreme's efficacy claims was inadequate and that the tests Thompson relied on were flawed. (*See, e.g.*, CXs 88, 89, 90-91). Also in and around 1980, Thompson became aware of four studies—Roth (CX 344Z-195), Ehrlich (CX 344Z-157), Charles (CX 344Z-168), and Brown (CX 344Z-182)—showing no statistical difference between TEA/S and placebos. In 1981, the director of the FDA's Division of OTC Drug Evaluation told Thompson that TEA/S had not been shown effective. His comments are particularly significant because he reviewed the clinical studies Thompson had submitted to the FDA after publication of the OTC external analgesics panel's report, the same studies Thompson has submitted to us. He wrote to Thompson that these studies were all deficient to prove Aspercreme's efficacy (CX 342; *see also* CX 343). Again in 1983, with the adoption of its tentative final monograph (CX 443), the FDA concluded that TEA/S has not been [97] proven effective. Through all of this, Thompson steadfastly argues that the scientific experts it employed (*e.g.*, the persons who performed the defective studies) believed TEA/S to be effective, that its studies are valid, that its other evidence (such as a 1981 non-projectable survey of pharmacists by a magazine, a survey critiqued by the ALJ in IDFs 369-71) is adequate to support efficacy claims, and that it is acting in good faith when it continues to rely on this evidence. Our reading of the record is that Thompson has known or should have known for some time now that its efficacy claims for Aspercreme are unsubstantiated. We further conclude that Thompson has deliberately continued making efficacy claims despite this fact.

Likewise, it seems clear that Thompson deliberately sought to lead consumers into the belief that Aspercreme contains aspirin. Again, Thompson had good reason to know that one reasonable interpretation of the product's labeling and advertising was that it contains aspirin. The company was warned of this possibility by the results of two focus group studies that it had available to it as early as 1978—the Nicholas and [98] Schneider focus groups.[82] Consumer belief in aspirin content also clearly was indicated by the results of the Mapes & Ross copy test in 1979 (CX 50), which examined the earliest Aspercreme [99] TV ads (CXs 1 and 2).[83] The possibility of such a net impression was further communicated to Thompson by the television networks and NAB in 1979 and 1980 (*See, e.g.*, CXs 79, 80, 88D).

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[82] The Nicholas focus group study (CX 52) was conducted in 1973 with two groups of eleven women, all of whom suffered from arthritis or some form of muscular aches and pains and all of whom were users of either topical analgesics or aspirin. The Schneider focus group study (CX 53) was conducted in 1978 with three groups of respondents (two groups of females and one group of males), all of whom used some sort of internal tablets or external rubs for arthritis relief. Participants in both the Nicholas and Schneider focus group studies were recruited and asked to use Aspercreme for at least ten days prior to the focus group sessions.

Because focus group studies are conducted with very few respondents obtained through [illegible] samples, and because the interviews are conducted in an unstructured group format, it is difficult to [illegible] generalizable conclusions from them. Indeed, it is not unusual to obtain conflicting results from focus groups. [illegible] at note 34 above. (One explanation for such conflicting results is that the moderator's control [illegible] can skew them toward a particular result. It might be, therefore that 90% of the participants in [illegible] (9 out of 10 people) thought of "aspirin" as a particular chemical, and in another only 10% [illegible] survey would show 60% of the general population to hold that belief.) Accordingly, we do not [illegible] to have treated these focus groups [illegible]

The fact that the ads created a net impression of aspirin content appears to have been no accident. The document "Aspercreme Brand Review," prepared for Thompson by Ogilvy & Mather in July, 1980 (CX 54), shows the purpose of Aspercreme advertising was to communicate that Aspercreme is aspirin in a rub.[84] Moreover, when the networks insisted on a revision of the early TV ads to reduce the incidence of mistaken beliefs, and Thompson accordingly approved ads with supers stating "contains no aspirin" and "relief without aspirin" (CXs 3 and 4), it appears that Thompson continued to use the audio phrase "relief of aspirin" in the revised ads hoping that the phrase would [100] offset the disclaimer.[85] Thompson also made no attempt to test whether or not the disclosures in CXs 3 and 4 were effective.[86] In addition, Thompson apparently continued to use CX 9 and related TV commercials (the ones with the disclosure "contains no aspirin, a strong non-aspirin pain reliever") after the completion in early 1981 of consumer research that it had sponsored and from which it should have realized that the ads communicated a message that Aspercreme contains aspirin.[87] All of this conduct is evidence that

Thompson has known full well for some time that consumers misunderstood the identity of the principal ingredient in Aspercreme and has continued to advertise in a manner that creates more such misunderstanding.

In addition, the "adaptability or transferability" of Thompson's violations to other products convinces us that a fencing-in order is appropriate. The scope of the order in this [101] case is similar to those in *American Home Products*, *Bristol-Myers*, and *Sterling Drug*. Those were cases that also involved claims for analgesic products. Our comments in *American Home Products*, 98 F.T.C. at 405, are equally apposite here: "The effort to misrepresent the nature of . . . [an] ingredient is a technique that could easily be applied to advertising of OTC drug products other than [this one]." Likewise, claims that tests prove a product's superiority or claims that its active ingredient is a breakthrough could readily be employed for any non-prescription drug product. Accordingly, it is necessary that Part I of this order apply to all such OTC drug products.

Part II of the order is narrower in scope than Part I, being limited to OTC analgesic drugs. It is so limited because our factual findings go only so far as to conclude that two well-controlled clinical tests are necessary as a reasonable basis for analgesic efficacy claims. Conversely, however, this analysis makes clear that no lesser standard than two well-controlled clinical tests is appropriate as a general rule for any analgesic product, whether its active ingredient is TEA/S or something else. It also is clear there is nothing inherently unique about Aspercreme or TEA/S to prevent Thompson from transferring the practice of claiming efficacy without such proof to other OTC analgesics. Thus, a fencing-in provision is warranted.

Finally, we comment on one order provision that complaint counsel urged upon the ALJ as well as upon us and that both he and we have rejected. It is an order provision that would [102] require Thompson to excise the "Aspercreme" brand name. Complaint counsel have asserted that brand name excision is a remedy the Commission has employed in the past when a brand name was deceptive and when no less restrictive alternative would suffice to eliminate deception (CAP 23-26). Complaint counsel further argue that such is the case here.

We agree with complaint counsel that brand name excision is a remedy available to us for use in extreme circumstances.[88] We do not find, however, that complaint counsel have made a sufficient case to warrant employing the remedy here. To order brand name excision, we would have to be persuaded that a less severe remedy, such as

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content in Aspercreme. However, the focus groups did provide Thompson with exploratory information about those beliefs. The results of both the Nicholas and the Schneider focus group studies were consistent in demonstrating that there was a high probability that participants would believe Aspercreme contains aspirin. Indeed, the final reports of both studies contain quotes that emphasize an aspirin association. For example, the Nicholas report states that one participant said, "When I saw it and saw 'Asper,' I right away thought it had aspirin in it. . . ." (CX 52-L) and the Schneider study states "in addition, others felt they were attracted by 'Asper' Aspercreme' because 'it has aspirin in it' or is 'full of aspirin.'" (CX 53-Z36) Thus, both the Nicholas and Schneider focus group studies indicate that even after using Aspercreme for at least ten days several of the focus group participants believed that Aspercreme contained aspirin. The consistency of this finding across both studies should have been a warning signal to Thompson that potential consumers might be confused about the ingredients of Aspercreme.

[83] As discussed above, at pp 20-22, results from the Mapes and Ross Test indicated that between 21 and 35 percent of persons viewing CXs 1 and 2 believed Aspercreme contained aspirin.

[84] *See, e.g.*, CX 54Z-006

Creative Strategy

> The creative objective is to convince arthritis sufferers - men and women over 50 - that Aspercreme is the arthritis medicine that puts all the relief of aspirin directly at the point of pain.
>
> The reason why is that Aspercreme contains the pain relieving ingredient of aspirin in a penetrating carrier which is taken quickly through the skin into painful joints and muscles.

[85] A [illegible] conference report summarizing a meeting between Thompson and Ogilvy & Mather (CX 66) to discuss [illegible] new ads states: "The client [Thompson] agreed [to TV ads with supers] and will pursue approval of the [illegible] equivalency claim. In the meantime the agency [Ogilvy & Mather] will pursue the 'strong relief of aspirin' [illegible] to offset the contains no aspirin super.")

[86] Thompson has suggested to us that "the networks accepted these supers because they were sufficient to clarify any possible ambiguity" (RAB 47). This is not the case. At least one network warned that the supers were ineffective. *See* CX [illegible] letter from Director of Commercial Clearance for CBS to Thompson: "In the new tape the super 'relief without aspirin' accomplishes little and may only serve to confuse the issue. For that reason, we have decided not to accept the revision but to remain with the original for a period of two months, until January 15. [illegible] By that time, we will hope for some better-defined message which can avoid the present difficulty."

[87] [illegible] Discussion, supra at 35-38.

[88] *See, e.g.*, *FTC v. Algoma Lumber Co.*, 291 U.S. 67 (1934); *Resort Car Rental System, Inc. v. FTC*, 518 F.2d 962 (9th Cir.), *cert. denied*, 423 U.S. 827 (1975); [illegible] *Corp. v. FTC*, 302 F.2d [illegible] (1962); [illegible]

affirmative disclosures, could not correct the misimpression that Aspercreme contains aspirin. Complaint counsel have argued that the evidence in this case leads to such a conclusion (CAP 34–38). However, we do not find that this evidence justifies brand name excision. The evidence consists in part of the testimony by complaint counsel's marketing expert. He stated that the brand name is the most salient part of a commercial to consumers and that, therefore, the misperceptions generated by the brand name "Aspercreme" cannot be overcome by any disclaimers included in ads (CAP 34–36). This line of reasoning appears to prove too much. It leads to the conclusion that the Commission must ban any brand name suggesting an [103] ingredient not contained in the product. As Thompson has pointed out, however, there are numerous products on the market whose names suggest an ingredient they do not contain.[89] While no evidence is before us showing whether or not consumers are confused by those names, we think it probable that a properly designed ad campaign for such products, or for Aspercreme, could convey to consumers the message that the product is similar to but not identical with the ingredient suggested by the brand name. In any event, we are not willing to discount this possibility based upon one expert's opinion.

The other evidence cited by complaint counsel (CAP 36–38) consists of the surveys on the record showing Thompson's TV disclosures that Aspercreme does not contain aspirin were [104] ineffective.[90] Complaint counsel argue this shows disclosures cannot work. However, complaint counsel agree with the ALJ and with us that Thompson's disclosures were "woefully insufficient" (CAP 37). Evidence that a

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[89] See RAB 41.

The marketplace abounds with products whose marks suggest but do not describe a character or quality of the goods, as for example Bacos (no bacon), Sugar Twin (no sugar), Egg Beater (no egg), Cremora (no cream), Silkience (no silk), Cottonelle (no cotton), Tuna Twist (no tuna), Chock Full O'Nuts (no nuts), Chicken of the Sea (no chicken), Apple Beer (no beer), and Rubbermaid (no rubber) (Ross, Tr. 6083–6086; Silver, Tr. 5663–5664). The common sense "message" inherent in these names is "similar to", i.e., similar to bacon, similar to sugar, etc.

[90] We have discussed these surveys, CXs 27, 32 and 36, above. It is arguable that another survey sponsored by complaint counsel, the ASI Interlock Experiment (CX 26), provides information about whether the brand name Aspercreme inherently leads consumers to believe Aspercreme contains aspirin. However, we do not believe that the survey supports such a conclusion. The objective of CX 26 was "to find out whether or not the name Aspercreme led consumers to the inference that this product contained aspirin as an ingredient." (CX 26-B) The research design involved showing each respondent a single stimulus which included the name Aspercreme, Ben-Gay or Mobisyl as well as the phrase "for the temporary relief of minor arthritic pain" (CX 26-C). They were then asked, "What ingredient or ingredients are suggested by the name ____?" (CX 26-Z32). We find this question to be ambiguous given the nature of the objective of CX 26 because the wording is not equivalent to asking people whether they believe a topical analgesic for the temporary relief of minor arthritic pain contains aspirin. This ambiguity can be illustrated with the following example. If people were asked what ingredients were suggested by a cigarette with the name "Old Gold" the response "gold" would be expected from many. If they were instead asked what ingredients the product contained, we would expect that very few would reply "gold." The question in CX 26 is similarly flawed. Additionally, the ambiguity in CX 26 was probably heightened because respondents were not told that Aspercreme is a topical analgesic rather than one that is taken internally. Therefore CX 26 does not provide probative evidence regarding whether the brand name Aspercreme causes reasonable consumers to believe that aspirin is an ingredient in Aspercreme. In addition, nothing in CX 26 tests whether or not any incipient potential for misperception could be overcome by disclosures.

poorly designed disclosure is ineffective, an unsurprising result, does not prove the inability of a well-designed disclosure to communicate a message to consumers. [105]

VI. CONCLUSION

For the reasons set forth above, we affirm the administrative law judge's finding of liability and modify his initial decision as described.

APPENDIX

FTC POLICY STATEMENT REGARDING ADVERTISING SUBSTANTIATION

Introduction

On March 11, 1983, the Commission published a notice requesting comments on its advertising substantiation program.[1] To facilitate analysis of the program, the notice posed a number of questions concerning the program's procedures, standards, benefits, and costs, and solicited suggestions for making the program more effective. Based on the public comments and the staff's review, the Commission has drawn certain conclusions about how the program is being implemented and how it might be refined to serve better the objective of maintaining a marketplace free of unfair and deceptive acts or practices. This statement articulates the Commission's policy with respect to advertising substantiation. [2]

The Reasonable Basis Requirement

First, we reaffirm our commitment to the underlying legal requirement of advertising substantiation—that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated.

The Commission intends to continue vigorous enforcement of this existing legal requirement that advertisers substantiate express and implied claims, however conveyed, that make objective assertions about the item or service advertised. Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims. These representations of substantiation are material to consumers. That is, consumers would be less likely to rely on claims for products and services if they knew the advertiser did not have a reasonable basis for believing them to be true.[2] Therefore, a firm's failure to possess and rely [3] upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.

Standards for Prior Substantiation

Many ads contain express or implied statements regarding the amount of support the advertiser has for the product claim. When the substantiation claim is express (e.g., "tests prove", "doctors recommend", and "studies show"), the Commission expects the firm to have at least the advertised level of substantiation. Of course, an ad may imply more substantiation than it expressly claims or may imply to consumers that the firm has a certain type of support; in such cases, the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers.

Absent an express or implied reference to a certain level of support, and absent other evidence indicating what consumer expectations would be, the Commission assumes that consumers [4] expect a "reasonable basis" for claims. The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable. Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses.

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[1] 48 FR 10471, March 11, 1983.

[2] Nor presumably would an advertiser have made such claims unless the advertiser thought they would be material to consumers.

One issue the Commission examined was substantiation for implied claims. Although firms are unlikely to possess substantiation for implied claims they do not believe the ad makes, they should generally be aware of reasonable interpretations and will be expected to have prior substantiation [5] for such claims. The Commission will take care to assure that it only challenges reasonable interpretations of advertising claims.[3]

Procedures for Obtaining Substantiation

In the past, the Commission has sought substantiation from firms in two different ways: through industry-wide "rounds" that involved publicized inquiries with identical or substantially similar demands to a number of firms within a targeted industry or to firms in different industries making the same type of claim; and on a case-by-case basis, by sending specific requests to individual companies under investigation. The Commission's review indicates that "rounds" have been costly to both the recipient and to the agency and have produced little or no law enforcement benefit over a case-by-case approach. [6]

The Commission's traditional investigatory procedures allow the staff to investigate a number of firms within an industry at the same time, to develop necessary expertise within the area of investigation, and to announce our activities publicly in circumstances where public notice or comment is desirable. The Commission intends to continue undertaking such law enforcement efforts when appropriate. However, since substantiation is principally a law enforcement tool and the Commission's concern in such investigations is with the substantiation in the advertiser's possession, there is little, if any, information that the public could contribute in such investigations. Therefore, the Commission anticipates that substantiation investigations will rarely be made public before they are completed.

Accordingly, the Commission has determined that in the future it will rely on nonpublic requests for substantiation directed to individual companies via an informal access letter or, if necessary, a formal civil investigative demand. The [7] Commission believes that tailored, firm-specific requests, whether directed to one firm or to several firms within the same industry, are a more efficient law enforcement technique. The Commission cannot presently foresee circumstances under which the past approach of industry-wide rounds would be appropriate in the ad substantiation area.

Relevance of Post-Claim Evidence in Substantiation Cases

The reasonable basis doctrine requires that firms have substantiation before disseminating a claim. The Commission has on occasion exercised its discretion, however, to consider supporting materials developed after dissemination.[4] The Commission has

not previously identified in one document the circumstances in which it may, in its [8] discretion, consider post-claim evidence in substantiation cases.[5] Such guidance can serve to clarify the program's actual operation as well as focus consideration of post-claim evidence on cases in which it is appropriate.

The Commission emphasizes that as a matter of law, firms lacking a reasonable basis before an ad is disseminated violate Section 5 of the FTC Act and are subject to prosecution. The goal of the advertising substantiation requirement is to assure that advertising is truthful, however, and the truth or falsity of a claim is always relevant to the Commission's deliberations. Therefore, it is important that the agency retain [9] the discretion and flexibility to consider additional substantiating evidence, not as a substitute for an advertiser's prior substantiation, but rather in the following circumstances:

- When deciding, before issuance of a complaint, whether there is a public interest in proceeding against a firm;
- When assessing the adequacy of the substantiation an advertiser possessed before a claim was made; and
- When deciding the need for or appropriate scope of an order to enter against a firm that lacked a reasonable basis prior to disseminating an advertisement.

First, using post-claim evidence to evaluate the truth of a claim, or otherwise using such evidence in deciding whether there is a public interest in continuing an investigation or issuing a complaint, is appropriate policy. This does not mean that the Commission will postpone action while firms create post-claim substantiation to prove the truthfulness of claims, nor does it [10] mean that subsequent evidence of truthfulness absolves a firm of liability for failing to possess prior substantiation for a claim. The Commission focuses instead on whether existing evidence that claims are true should lead us in the exercise of our prosecutorial discretion to decline to initiate a law enforcement proceeding. If available post-claim evidence proves that the claim is true, issuing a complaint against a firm that may have violated the prior substantiation requirement is often inappropriate, particularly in light of competing demands on the Commission's resources.

Second, post-claim evidence may indicate that apparent deficiencies in the pre-claim substantiation materials have no practical significance. In evaluating the adequacy of prior substantiation, the Commission will consider only post-claim substantiation that sheds light on pre-existing substantiation. Thus, advertisers will not be allowed to create entirely new substantiation simply because their prior substantiation was inadequate. [11]

Finally, the Commission may use post-claim evidence in determining the need for or appropriate scope of an order to be entered against a firm that lacked a reasonable basis. Thus, when additional evidence offered for the first time at trial suggests that the claim is true, the Commission may frame a narrower order than if there had been no post-claim evidence.

The Commission remains committed to the prior substantiation requirement and further believes that these discretionary factors will provide necessary flexibility. The Commission will consider post-claim evidence only in the circumstances listed above. But, whether it will do so in any particular case remains within its discretion.

Self Regulation Groups and Government Agencies

The Commission traditionally has enjoyed a close working relationship with self-regulation groups and government agencies whose regulatory policies have some bearing on our law enforcment initiatives. The Commission will not necessarily [12] defer, however, to a finding by a self-regulation group. An imprimatur from a self-regulation group will not automatically shield a firm from Commission prosecution, and an unfavorable determination will not mean the Commission will automatically take issue, or find liability if it does. Rather the Commission will make its judgment independently, evaluating each case on its merits. We intend to continue our useful relationships with self-regulation groups and to rely on the expertise and findings of other government agencies in our proceedings to the greatest extent possible.

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[3] Individual Commissioners have expressed differing views as to how claims should be interpreted so that advertisers are not held to outlandish or tenuous interpretations. Notwithstanding these variations in approach, the focus of all Commissioners on reasonable interpretations of claims is intended to ensure that advertisers are not required to substantiate claims that were not made.

[4] The Commission's evidentiary rule, 16 C.F.R. 3.40, has sometimes been interpreted as precluding introduction of post-claim substantiation. In fact, it does not. Section 3.40 only provides a sanction against the introduction of evidence that should have been produced in response to a subpoena, but was not.

[5] The distinction between pre-claim and post-claim evidence is only relevant when the charge is lack of substan-[illegible] tion. For [illegible]

By direction of the Commission.

FINAL ORDER

The matter has been heard by the Commission upon the appeal of counsel for respondent Thompson Medical Company, Inc. and complaint counsel and upon briefs and oral argument in support of and in opposition to the appeals. The Commission, for reasons stated in the accompanying Opinion, has granted a portion of complaint counsel's appeal and denied that of respondent. Therefore

It is ordered, That the initial decision of the administrative law judge be adopted as the Findings of Fact and Conclusions of Law of the Commission except as is otherwise inconsistent with the attached Opinion.

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered, That the following Order to Cease and Desist be entered:

ORDER

I

It is ordered, That respondent, Thompson Medical Company, Inc., a corporation, its successors and assigns, and respondent's officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, [2] sale or distribution of any over-the-counter "drug" as that term is defined in the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Employing the brand name "Aspercreme" for such products or otherwise representing directly or by implication that an active ingredient of such product is aspirin, unless such product contains aspirin in therapeutically significant quantities; *provided, however*, that the brand name "Aspercreme" may be used for such product if its

advertising and labeling clearly and prominently disclose that the product does not contain aspirin.

(1) In television advertisements, an explicit and simple aspirin disclaimer statement (such as "ASPIRIN-FREE") shall be superimposed on the television screen simultaneously with a vocal aspirin disclaimer statement (such as "Aspercreme does not contain aspirin") at the end of each advertisement.

(2) In radio advertisements, an explicit aspirin disclaimer statement (such as "Aspercreme does not contain aspirin") shall be made at the end of each advertisement.

(3) In print advertisements, an explicit aspirin disclaimer statement (such as "ASPERCREME DOES NOT CONTAIN ASPIRIN") shall be displayed prominently and conspicuously in relation to each such advertisement as a whole.

(4) In labeling, an explicit aspirin disclaimer statement (such as "DOES NOT CONTAIN ASPIRIN") shall be prominently and conspicuously printed in the front package panel (or in the front of the container if no package is used).

B. Representing, directly or by implication, that such product involves a new scientific principle, when such product or one involving such principle has been available for purchase in the United States as an over-the-counter drug for more than one year. [3]

C. Misrepresenting the contents, validity, results, conclusions, or interpretations of any test or study.

D. Misrepresenting the identity of the active ingredient(s) in such product.

II

It is further ordered, That Thompson Medical Company, Inc., a corporation, its successors and assigns, and respondent's officers, representatives, agents, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any OTC analgesic "drug," as that term is defined in the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing that such product is effective for the relief of minor pain and other symptoms of any musculoskeletal disorder (such as arthritis, tendonitis, bursitis, or rheumatic disorders).

B. Representing that such product is as fast as or faster than, or is as effective as, or more effective than any other drug or device in the relief of minor pain and other symptoms of any musculo-skeletal disorder (such as arthritis, tendonitis, bursitis, or rheumatic disorders),

unless at the time of the dissemination of any such representation, respondent possesses and relies upon a reasonable basis for such representation consisting of competent and reliable scientific or medical evidence. For analgesic drug products competent and reliable scientific or medical evidence shall include at least two adequate and well-controlled, double-blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, independently of each other. Such persons shall be qualified by training and experience to conduct such studies. *Provided however*, with respect to any representation covered by this part other than claims of superior or comparative effectiveness or safety, if the Food and Drug Administration promulgates any final standard which establishes conditions under which such product is safe and effective under the Food, Drug and Cosmetic Act, then in lieu of the above, respondent may rely upon scientific evidence which fully conforms to such final standards as a reasonable basis for said representation. [4]

III

It is further ordered, That so much of the complaint as relates to Paragraph 12 (f) be, and the same hereby is, dismissed.

IV

It is further ordered, That respondent Thompson Medical Company, Inc. shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation such as a dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in its corporation which may affect compliance obligations under this Order.

V

It is further ordered, That the respondent herein shall within sixty (60) days after service of this Order upon it and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which it has complied or intends to comply with this Order.

State of Kansas

Office of
HARD G. GANNON, EXECUTIVE DIRECTOR
K. ABBOTT, ADMINISTRATIVE ASSISTANT
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Board of Healing Arts

August 2, 1989

Mr. Daniel Oliver, Chairman
Federal Trade Commission
Washington, D.C. 20580

Dear Chairman Oliver:

Thank you for your most recent attempt to "correct some misapprehensions" that the Kansas Board of Healing Arts might have about the Federal Trade Commission. Since many of our sister states share Kansas' concerns about Federal/State interaction in medical advertising, perhaps a clarification of the Federal Trade Commission's position at a multi-state forum would be in order. I might suggest that the National Clearinghouse on Licensure, Enforcement and Regulation (CLEAR), has scheduled for its 9th annual conference September 6-8, 1989, at Indianapolis, Indiana, and also the Federation of State Medical Boards of the United States, Inc., will hold its annual meeting in April 26-28, 1990, in Birmingham, Alabama.

In any event, I am optimistic that our two organizations can work together toward mutual goals. Noteworthy is my recent request for formal opinion on whether an advertisement by the National Institute of Clinical Acupuncture would be in violation of the Federal Trade Commission policies and rules. The response by Richard Kelly, Assistant Director, Bureau of Consumer Protection, was extremely prompt, precise and helpful.

Once again, thank you for your letter as well as Mr. Kelly's prompt response to my request.

I am sincerely,

Richard G. Gannon

Richard G. Gannon (State Senator, Ret.)
Executive Director

RGG/pd

cc: Richard F. Kelly
Assistant Director

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Federal Trade Commission

3014828

THE HONORABLE DANIEL OLIVER

CHAIRMAN

FEDERAL TRADE COMMISSION

"REPORT FROM OFFICIAL WASHINGTON ON THE STATE OF ADVERTISING IN 1988"

Before the

AMERICAN ADVERTISING FEDERATION'S

SPRING GOVERNMENTAL AFFAIRS CONFERENCE

The Ballroom
The Willard Hotel
Washington, D.C.

Tuesday, March 15, 1988

Thank you, Wally. It is a pleasure to be invited back to the Federation's Government Affairs Conference. You've given me the chance to make good on an advertised claim. As you know, last year I used this occasion to give my first annual address on the state of advertising regulation. Thanks to you, it was not to be the last annual address. Before I begin my remarks today, truth in advertising requires that I make the following disclosure: my comments do not necessarily represent the views of the Commission.

Last year, as you may recall, I described how the conventional wisdom about advertisers and consumers evolved over the past few decades. In the fifties the only people who, it was said, really "understood" advertising were academics who assumed advertising was a symptom of a sick society. There were few dissents to the notion that commercial information at best was an expensive waste of time, talent, and money. At worst, advertising was said to be a powerful, misguided force that served mainly to foist undesirable products on hapless consumers. Where there was such waste and manipulation, regulators, of course, could not be far behind. Clearly, consumers needed government protection.

Slowly, this view of advertising was exposed as the nonsense it is. First there was a breakthrough in academic research. A few renegade economists and marketing professors claimed to have found signs of intelligence in consumers. Then came the discovery that intelligent people would use information. These discoveries challenged the prevailing assumptions that consumers possessed all the information they needed, but lacked the ability to understand it.

I know none of this came as any surprise to you. You are the ones who are paid to appeal to consumers. You are the ones who work hard to win their loyalty. You are the ones who pay the price when consumers just say no to your brilliant campaigns.

But regulators resisted the new, enlightened view of advertising. Their power depended on the notion that consumers were unintelligent and were beleaguered by advertisers. But if there was any doubt about the intelligence of consumers, the consumers themselves dispelled it in the election of 1980. The national nannies got their walking papers, and regulation got an overhaul that was long overdue.

And so last year at this conference, it was easy to be optimistic. We were still enjoying the election rewards of 1980 and 1984, and the season in which the regulators advertise themselves was still a year away. Before I review the high and low points of this past year, remember that last year I pointed out three trends that posed serious threats to your industry.

Those threats were the growing interest in censorship; the increasing balkanization of advertising regulation; and the reappearance of the super-regulator.

I am happy to be able to say that the advertising community, and the public at large, won a very important battle this past year against the proponents of censorship. Congressional hearings on a cigarette advertising ban played to capacity crowds. I said at one of those hearings that the choice between keeping information freely available for consumers and suppressing information "for their own good" was the choice between consumer sovereignty and censorship. I cast my vote for informed consumers. And the good news is that the attempt to impose a ban on cigarette advertising failed again last year.

This year, the tide may have turned. For example, the Food and Drug Administration is considering reversing its longstanding policy on banning health claims on food labels. Now, for the first time, the FDA proposes to move on behalf of consumers to allow manufacturers to provide consumers with accurate and truthful information about food -- the same kind of information we have been allowing food manufacturers to disseminate to consumers in advertising for years.

Regrettably, not everyone greeted this news with enthusiasm. But then sometimes the advocates of censorship pop up in the most surprising places. How many publications would you expect to support the proposition that the government should either clear speech in advance or ban it altogether? Would you believe the New York Times would support preclearance? The Times objected to the FDA's proposal and recommended that the agency continue either to ban all health claims or pre-screen them.[1] Imagine, if you can, the Times' reaction to a proposal that its news and editorials be cleared by the government before being printed -- in order to avoid confusing readers.

I guess I shouldn't be surprised that the friends of censorship have strange bedfellows. Advertising is a highly visible bogeyman and an easy target. That is why I say that although we may have won yesterday's battles, the war is not yet over.

Last year I spoke about the threat of balkanization: where a single state can effectively erect a total barrier to commerce in the rest of the 49 states. We saw a classic example of that threat last year in the field of fast food advertising.

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[1] "The Snake Oil Diet," New York Times, August 10, 1987, p. A-18.

Last year, the fast food industry began to experiment with nutritional advertising. Fresh from the lean-burger battlefield, one hamburger chain began to disclose all kinds of nutrients in its foods. But, unfortunately, certain state AGs started to cry foul. Suddenly, this advertising of nutrition just . . . stopped. Confronted with the prospect of being tried in the press, fast food providers completely abandoned this kind of advertising. I guess you can't advertise nutrition if you sell burgers. Which is a shame -- because it means consumers will be less aware of nutritional matters.

Why lament the end of this kind of advertising? Well, if one wants to see a dramatic improvement in the nutritional composition of fast foods, one could scarcely think of a better was of bringing it about than through nutritional advertising. If one fast food chain advertises the nutritional advantages of some of its foods, and consumers react favorably, do you think the other chains will concede this market segment? Of course not! We've seen this happen before. Consider the introduction of diet soft drinks and caffeine-free soft drinks.

Now I don't want my remarks misinterpreted. I'm not suggesting that the fast food industry has carte blanche at the Federal Trade Commission to represent that its foods are healthier than health foods -- whatever health foods are. But what I am saying is that it makes no sense to tell a Chevy dealer not to advertise comfort because Cadillacs are more comfortable.

The nutrition advertising episode reminds me, in some ways, of what happened in the cigarette industry back in the early sixties when some of the cigarette manufacturers began to advertise the tar and nicotine content of their products. You may ask why would a cigarette company do such a thing? Well, a number of companies decided that lowering their tar and nicotine content might be an effective way to compete. Sure enough it was, and tar and nicotine levels began to fall, providing consumers with new choices in cigarettes. Unfortunately, when the FTC of that day decided to ban tar and nicotine advertising, tar and nicotine levels began to level off. Advertising was the only effective way manufacturers had to sell their innovative lower tar and nicotine cigarettes. Not surprisingly, when the ban was lifted several years later, tar and nicotine levels once again began to fall significantly.

Almost as disappointing as the enforcement approach adopted by certain states regarding fast food advertising was the reaction of the industry. Instead of rallying to fight against the suppression of nutritional information, the industry abandoned this kind of advertising quicker than you can say "two all-beef patties, special sauce, lettuce, cheese, pickle, onion on a sesame seed bun."

In addition to the threat of inconsistent state regulation, we now face the threat of consistent state regulation that is at odds with Federal regulation. Last year I predicted that, as legislatures ran out of money to tax and spend, we would see more regulatory activity, because the burden of complying with regulations is less visible than new taxes would be. Well, that is precisely what is occurring. The fifty states are adopting regulations that are more restrictive than Federal regulations were before the enlightenment.

Where did the states, flexing their regulatory muscles, decide to strike first? In an area where consumer complaints seldom appeared on the radar screens of ad traffic controllers. It came in the area of airline advertising.

Now, obviously, it's more crowded up there in the skies than it used to be. As Chairman of a consumer protection agency, I certainly see nothing wrong with the benefits of air travel being made available to increasing numbers of consumers, even if, as a customer, I am no longer as pampered as I used to be. But there is something seriously wrong with an attempt to regulate this industry by attacking its advertising.

How serious is the problem of deceptive airline advertising? Let me describe its earthshaking proportions. Last year, over 390 million passengers took domestic flights. During the same time, the Department of Transportation received 411 advertising complaints from passengers. That means that there was approximately one advertising complaint received per million air travellers. Yet, the states have claimed that airline advertising complaints have reached crisis proportions. If there is a crisis here, it is the crisis of politicians who look in the part of the cupboard marked "issues," and find the cupboard bare.

The National Association of Attorneys General has developed guidelines to address this advertising non-problem.[2] What kind of advertising prompted these ad traffic controllers to action? Let me give you an example of one of the blips on their radar screens. Here's a blip, or ad, that promoted a reduced fare to London. The NAAG apparently thought it was deceptive because the restrictions were not sufficiently spelled out. The restrictions read:

> Seats limited. Expiration dates vary. Fares each way based on roundtrip purchase, subject to change, government approval. Not available during certain holiday periods. Advance purchase, weekend surcharges, cancellation, change of date/itinerary penalties and

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[2] NAAG Task Force on the Air Travel Industry, Final Report and Recommendations (1987).

other restrictions apply. Fuel/security surcharge, $3 international departure tax, customs fees not included. Most U.S. fares non-refundable.

Can you imagine a politician seeking election caveating his campaign promos in such a fashion?

In all likelihood, the National Association of Attorneys General guidelines will substantially and unnecessarily inhibit price competition, depriving consumers of billions of dollars of savings each year. Advertising plays a critical role in allowing airlines to inform consumers of their lower prices and new types of discounts. Take that advertising away and you effectively end price competition.

The Commission has long recognized that omission of material information can make an advertisement or representation unfair or deceptive.[3] But Commission decisions also recognize that this principle must be applied in a manner that will not stifle truthful advertising.[4] Fifteen-second and thirty-second commercials are an important means of waging price competition, but they don't allow for detailed disclosures of every term and condition of the contract. The extensive disclosure requirements in the airline guidelines have already begun to dampen price competition. The Wall Street Journal reports that advertising of fares on television has been sharply curtailed ever since the guidelines went into effect,[5] and John Van De Kamp, the Attorney General of California, conceded as much last Sunday.

There have been some exceptions. One airline, in advertising its one-way fares, advised readers that the fares were based on a round-trip purchase. For the benefit of the regulators, the airline footnoted the fare with the proviso that, "for round-trip fare, multiply by 2." They hoped that was close enough for government regulators.

This footnote reminded me of an ad that Apple Computer ran about five years ago. In describing the portability of its new Apple IIc computer, the ad claimed that the unit weighed "less than 8 pounds." Placing an asterisk next to this claim, it added the following footnote: "Don't asterisks make you suspicious as all get-out? Well, all this one means is that the IIc alone weighs 7.5 pounds. The power pack, monitor, an extra disk drive, a printer and several bricks will make the IIc weigh more. Our lawyers were concerned that you might not be able to figure this out for yourself."

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[3] See e.g., International Harvester Co., 104 F.T.C. 949, 1055-62 (1984).

[4] See, e.g., id.; ITT Continental Baking Co., 83 F.T.C. 865, 965 (1973).

[5] "TV Networks Balking at Ad Guidelines on Disclosure of Air Fare Restrictions," Wall Street Journal, February 9, 1988, p. 44.

The authors of the NAAG guidelines want to placate passengers who discover they paid more than their neighbors. I will concede that it's aggravating when you can't book a seat at the lowest fare advertised on the day that you want to travel. It's even more aggravating when you find out that someone else got the low fare after you failed. Those are the realities of trying to fill an airplane before it takes off. The phenomenon is not unique to the airlines. We see it every year on Christmas-tree lots. We see it in produce markets. Indeed, we see it in just about any market for perishable products and services. Airline seats, after all, are perishable products -- like hotel rooms and roses.

The availability of discount fares depends on how many seats are likely to go to waste, given current demand. The number of seats available at different fares can change up to the time of departure, and of course cancellations may result in additional discount seats becoming available shortly before departure. Should we attack systems that give discounts to discretionary travelers -- to vacationers, retirees, and students -- who can adjust their travel plans, just so that we can save the busy executive the aggravation of discovering that he paid more? According to the National Association of Attorneys General guidelines, the answer apparently is yes.

We pointed out these and other problems with the guidelines to the Association during the short period of time we had to review the draft and the revised draft of the guidelines. If the Association had taken the opportunity to review their regulations with the benefit of various perspectives, perhaps these problems could have been solved. But unfortunately that was not the case. We read about these guidelines in the press weeks before we got them. When we finally received them, they were devoid of any supporting legal or factual analysis. If the Federal Trade Commission, after following the procedures the Association employed in drafting these guidelines, attempted to enforce these guidelines as a trade regulation rule, we'd be in Congress or in court defending ourselves by now. And the Commission is not the only federal agency troubled by the Association's rulemaking methodology. Last week Advertising Age reported that the Department of Transportation intends to go to court, if necessary, to block enforcement of the guidelines.[6]

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[6] "Feds Tell States to Back Off on Ad Restrictions," Advertising Age, March 7, 1988, p. 2.

There's good reason for the procedures that the Commission must follow in rulemaking. Those procedures force regulators to understand the consequences of what they're doing. Because airlines won't know the effect of these new NAAG regulations, and won't know what their legal liabilities are, they may go back to image advertising. And that would deprive consumers of the benefits of price advertising -- and price competition.

I've heard calls from your industry for the FTC to exert leadership.[7] Well, I think we have. And we will continue to do so. But keep in mind what I said last year: that one effort I will refuse to make is the effort to be the most restrictive regulator on the block.

There are a number of things that I will do, however. I will urge the Commission to bring the cases necessary to stop deception in national advertising. I will continue to speak out on behalf of sensible regulation. We will continue to advocate competition and rational regulation before other regulators, as long as we are allowed to, as long as Congress doesn't cater to the special interests and cut off our Consumer Advocacy Program. But I want to say this too: sometimes advocacy will not be enough. When it is not, I will urge the Commission to consider joining litigation that threatens consumers' access to accurate and valuable information.

I also want to say to you: stand up and speak out when you think your position is correct. Make your case for your right to inform consumers about what you do, and about what you want to sell. You, more than anyone else, can explain the value of advertising to consumers and to the economy. I have used my position as Chairman to speak out on the benefits of competition, on the value of free markets, but I can't do it alone. You must help.

I also encourage you to continue your efforts in self-regulation. The Council of Better Business Bureaus has urged state regulators concerned about airline ads to work through the Council's National Advertising Division.[8] The AAF has endorsed the idea, and I wholeheartedly add my own support. Let's hope the precedent is set before the NAAG moves on to rental car companies and fast food chains.

What trends do I foresee this year? Will we continue to enjoy the enlightened regulation that came to Washington in 1981?

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[7] See, "Big Mac Case Puts FTC On Griddle," Editorial, Advertising Age, May 11, 1987.

[8] Advertising Age, supra note 6.

Will regulators throughout the country recognize that requiring advertisers to provide more information can result in consumers' getting less information? Or will advertising copy for airlines, rental cars, or fast foods be written by politicians in state capitals across the country next year?

Perhaps, as we move into the advertising season for public officials, you should ask all those politicians who will be advertising themselves to the voters to keep in mind their own advertising the next time they are looking at yours. Is there anyone in this room who doesn't think that his product advertising at least meets the standards of honesty in advertising that politicians observe?

As we go into this political year, why don't you collect examples of political advertising that you think fail to meet the standards you apply in commercial advertising, and send those examples to me. Maybe I can find a use for them . . . someday . . . perhaps, when I'm up on Capitol Hill. Or perhaps we can swap war stories, next year, at your Spring Governmental Affairs Conference.

Federal Trade Commission

3023349

The Honorable Daniel Oliver

Chairman

Federal Trade Commission

before the

Health Law Forum
and the
Health Care Committee of the
Antitrust Section of the
American Bar Association

Washington, D.C.

September 30, 1988

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* The views expressed are those of the Chairman. They do not necessarily reflect those of the other Commissioners.

Good afternoon, and thank you for that kind introduction. As I think most of you know already, I'm from the government, and I'm here to help. After I've finished, you may conclude that I can't give you the kind of help you want. But that's the nature of my job. As the Chairman of the Federal Trade Commission, my primary function is to help consumers. Although helping consumers sometimes coincides with helping the firms and individuals that provide consumers with goods and services -- including your clients -- that's not always the case. In any event, I hope that I can at least help you to understand why the Commission has enforcement responsibilities in the health care area, and how it carries out those responsibilities.

The health care profession has changed substantially over the last two decades. Dramatic technological improvements appear more and more frequently, and there is every reason to think that the pace of technological innovation will continue. And as you all know, the business aspects of health care -- the ways that practitioners organise their practices, and the ways that consumers purchase medical services -- have also changed profoundly. Substantial increases in the number and variety of health care providers have created a heightened awareness that consumer desires must be understood and satisfied in order to attract and keep patients. At the same time, employers, unions, and the federal government's Medicare administrators have begun relying more and more on competition among health care providers to control health care costs. As a result, consumers have been presented with more choices, and more meaningful choices, in selecting health care providers.

The reason health care delivery systems have changed so markedly is that the free market has worked. Providers now realize that they can serve their own interests by responding quickly and efficiently to evolving consumer demands. Rising health care costs have made third-party payors more willing to shop around, and an increase in the supply of providers has generated strong competitive pressures. I find it particularly interesting and heartening that innovative methods of competition have emerged so rapidly in the health care sector, because health care has long been regarded as an industry unsuitable for competition. Until recently, deregulators had to spend most of their time arguing that competition should have *some* sort of role -- however small perhaps -- in the health care sector. There were so many regulations governing commercial behavior by professionals that government fiat, rather than competition, appeared to be the normal mechanism for allocating health care services.

Today, by contrast, virtually every issue of every health care publication has one or more articles about some aspect of health care competition. And the debate has shifted from whether competition should play *any* role at all to why *any* dimension of competition among qualified health care providers should be restricted.

That leads me to the question of the role that the Federal Trade Commission should play in the health care area. Our objective can be stated simply enough: it is to prevent health care providers from engaging in practices that injure competition. Now, if we could achieve our objective as simply as we can describe it, most of you would be practicing in some other field of law. The fact is, however, that the whole area of health care antitrust enforcement reeks of complexity. The Commission's job is to ensure that the market for health care services is truly competitive; that is, to ensure that the market is as free from public or private restraints as safety considerations permit. For consumers, this means the availability of as many different types of suppliers and services, offered at as many different prices, levels of quality, and degrees of convenience, as the market is willing to provide.

For health care providers, a competitive market means the ability to offer -- and to promote by disseminating truthful advertising -- any combination of products and services they wish, in whatever manner they choose. Government entities should interfere with business decisions only to the extent needed to ensure public safety and prevent anticompetitive behavior. More specifically, health care professionals in a truly competitive market should be able to do the following:

(1) Health care professionals should be able to offer, without unjustified restrictions, any service that they are licensed and qualified to provide;

(2) They should be able to join other providers in a group or clinical practice, and participate in HMOs and PPOs, without having to endure burdensome government regulations or unlawful retaliation from competing providers; and

(3) Health care professionals should be able to use truthful, non-deceptive advertising to inform patients and potential patients about their services, qualifications, prices, and all other relevant aspects of their practices.

Unfortunately, many health care professionals misunderstand the meaning of competition, and therefore misperceive much of what the Commission does in the health care area. It's true that we sometimes challenge agreements and activities undertaken by groups of health care professionals -- but only when those activities injure consumers. And let me emphasize here that the Commission does not attempt to interfere with the authority of state governments to protect public health and safety. Our field is competition, not medical science. Thus, we do not regulate state licensing systems, nor do we force states to permit medical procedures that they deem unsafe or inappropriate.

What most regulators don't realize is that regulatory efforts to promote and assure quality health care and patient safety need not sacrifice the benefits of competition. Indeed, a vitally important part of the Commission's efforts -- through its competition advocacy program -- involves helping federal and state governments to understand the consequences of regulation. Many restrictions imposed by law on health care providers needlessly interfere with health care delivery methods that could better respond to consumer demands. To the extent we find ourselves opposing doctors or other practitioners, it is not because we are against any particular group of health care professionals, but rather because it is our duty to advance consumer welfare by fostering competitive markets.

Well, at this point I could describe for you all of the Commission's cases and competition advocacy filings in the health care area during the last year. And I could recite a litany of the practices that health care providers should avoid because they may injure competition in one way or another. This might be the best approach, from your perspective. You could report to your clients that my speech had confirmed -- as if there were any doubt -- that health care antitrust enforcement is an angry sea, filled with dangerous rocks and shoals, in which only the most experienced practitioner can navigate.

I suspect, however, that you would rather be told what your clients can do than what they can't. The problem is that I can't give you definitive answers. I can't guarantee that the antitrust laws -- which are, after all, enforced through suits by private lawyers as well as by the Commission and the Department of Justice -- I can't guarantee that those laws definitely do not prohibit the use of any particular practice. Some of the situations I will discuss involve controversial issues that the courts, and most notably the Supreme Court, have not yet addressed directly. And you should also remember that my views don't necessarily reflect the opinion of my fellow Commissioners or of the Federal Trade Commission as an institution. If you want specific guidance about a specific activity that a client proposes to undertake, I suggest that you request an advisory opinion from the Commission.

I want to be as helpful as I can, however, and I can give you some more general affirmative guidance. Actors in the marketplace should be free to innovate and operate creatively without fear of government sanctions. Those of you who have heard me speak before know that I consider undue government regulation to be the greatest impediment to the efficient functioning of the marketplace. I hope that my remarks will help you to help your clients develop new, efficient, and procompetitive ways to provide and finance health care services.

Determining what competing physicians and other health care providers lawfully can do together requires a careful analysis of three relatively recent Supreme Court decisions: Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.,[1] Arizona v. Maricopa County Medical Society,[2] and NCAA v. Board of Regents of the University of Oklahoma.[3] In BMI, the Supreme Court considered the fact that the American Society of Composers, Authors, and Publishers ("ASCAP") issued blanket licenses at negotiated fees to broadcast copyrighted musical works by members and affiliates of BMI and ASCAP. The Court determined that this arrangement could not be characterized as per se illegal price fixing. Instead, its legality had to be determined under the rule of reason.

In reaching this conclusion, the Court recognized that BMI and ASCAP were organizations of composers and others who otherwise would compete with each other to "sell" to broadcasters licenses to perform their compositions. However, the Court found that enforcing copyrights on an individualized basis, and negotiating thousands of performance licenses, would be prohibitively costly and a "virtual impossibility." As a result, individual composers would be "inherently unable to compete ... effectively." Thus, in the Court's view, the defendants' blanket licenses had been created to facilitate rather than to suppress competition.

Moreover, the defendants' licensing operations reduced costs and achieved substantial efficiencies by reducing the number of licensing transactions and facilitating the prevention of copyright abuses. The Court noted that some type of bulk license was a "necessary consequence of the integration necessary to achieve those efficiencies," and that a "necessary consequence" of an aggregate license is that its price must be established. Furthermore, the Court found that the blanket license was "to some extent, a different product," something "quite different from anything any individual owner could issue." And finally, the Court emphasized that the blanket license was not exclusive; it did not prevent individual composers and authors from negotiating licensing arrangements on their own. On remand from the Supreme Court, the blanket licensing arrangement was found to be lawful.[4]

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[1] Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1 (1978) ("BMI").

[2] Arizona v. Maricopa County Medical Society, 457 U.S. 332 (1982) ("Maricopa").

[3] National Collegiate Athletic Association v. Board of Regents of the University of Oklahoma, 468 U.S. 85 (1984) ("NCAA").

In *Maricopa*, a 4-3 decision, the Supreme Court considered a medical society program under which physicians agreed to maximum prices that they would charge for health care services provided to policyholders under certain insurance programs approved by the physicians' medical care foundation. The Court concluded that this program amounted to *per se* illegal price fixing. Contrasting the physicians' arrangement to the blanket licenses in *BMI*, the Court observed that the physicians "sell medical services," and that "[t]heir combination in the form of the foundation does not permit them to sell any different product." The Court noted that the doctors and the foundation did not offer a new product, such as health insurance coverage, in connection with the joint sale of the services of individual physicians.

Because the physicians in *Maricopa* merely continued to sell their individual services through the foundation program, the Court concluded that establishing a fee schedule, even if desirable to insurers, was not essential to the success of the arrangement. The physician-established fee schedule therefore was held to be *per se* illegal price fixing, rather than a justifiable price restraint. This finding may have been colored to some degree by the Court's emphasis on the fact that the foundation program involved a very high percentage of local physicians.

More recently, in *NCAA*, the Supreme Court considered the exclusive contracts for televising college football games that the NCAA had negotiated with certain television networks. The Court recognized that the exclusive contracts restricted pricing and output, but declined to characterize the contracts as *per se* illegal. Instead, the Court considered the defendants' claimed justifications before concluding that the contracts were an unreasonable restraint of trade.

Relying in large part on the Supreme Court's decisions in *BMI* and *NCAA*, the Federal Trade Commission recently articulated a more elaborate analytical framework for evaluating horizontal business behavior in its *Massachusetts Board of Optometry* opinion.[5] You can expect the Commission to apply this analytical framework to horizontal restraints in the health care area. The framework contemplates developing answers to three questions. The first is whether the practice at issue is "inherently suspect"; that is, whether it's the kind of practice that is likely -- in the generality of cases, absent an efficiency justification -- to "restrict competition and decrease output." If the answer is "no," the Commission will apply the traditional rule of reason analysis to the practice.

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[4] *Columbia Broadcasting System, Inc. v. American Society of Composers, Authors and Publishers*, 620 F.2d 930 (2nd Cir. 1980), *cert. denied*, 450 U.S. 970 (1981), *reh'g denied*, 450 U.S. 1050 (1981).

[5] *Massachusetts Board of Registration in Optometry*, Docket No. 9195 (June 13, 1988), *reprinted in* 5 Trade Reg. Rep. (CCH) Para. 22,555 ("*Massachusetts Board*").

If the practice is inherently suspect, the second question the Commission will ask is whether there is a plausible efficiency justification for it -- that is, whether the practice might create or enhance competition by, for example, reducing costs or creating a new product. If the answer is "no," the practice can be condemned as a violation of section 5 of the Federal Trade Commission Act without further analysis. If, on the other hand, there is a plausible efficiency justification for the practice, the Commission will ask a third question: Is the proffered justification valid? If it is, the Commission will conduct a full rule of reason analysis. If it is not, the Commission will conclude without further inquiry that the practice violates Section 5.

The first two questions in the Massachusetts Board analysis contemplate three categories of joint conduct. First, there are agreements that, by their nature, are unlikely to restrict competition. I would typically subject these agreements to a full rule-of-reason analysis, whether or not the participants can immediately articulate a plausible efficiency justification. Examples might include a decision by independent doctors to establish a buying co-op for medical supplies, or to fund a non-profit corporation that would award research grants, or to create a standardized format for electronic exchange of patients' medical histories in referral situations.

The second category of behavior includes activities that, by their nature, are "inherently suspect;" that is, likely to restrict competition and reduce output in the generality of cases, but for which the participants have a plausible efficiency justification.

The third category of behavior includes "inherently suspect" activities for which the participants do not have an efficiency justification, plausible or otherwise.

The Massachusetts Board analytical framework poses some subtle issues that the Commission will probably have to address in the future. For example, one issue is how to define "plausible efficiency justification." Under the Massachusetts Board approach to horizontal restraints, horizontal competitors that have fixed prices in an inherently illegal fashion might now attempt to raise an efficiency defense in order to escape per se treatment. In general, I would not be inclined to characterize an asserted efficiency justification as "plausible" unless two criteria can be satisfied. First, the "inherently suspect" practices at issue should be ancillary to some form of economic integration. Second, the practices should be important to offering a new product or service. In referring to "new" products, of course, I mean to include "old" products or services that are offered in a new way. Thus, I would elaborate the Massachusetts Board analysis with the following caveat: an efficiency justification will be considered a "plausible" defense to "inherently suspect" behavior only if that behavior is important to permitting an economically integrated unit -- such as a joint venture -- to offer a new product or service.

Let me now suggest some types of collective conduct that, in my view, are not likely to violate either the per se prohibition enunciated in Maricopa or the elaborations of traditional rule-of-reason analysis set forth in BMI, NCAA, and Massachusetts Board. As I noted earlier, if the horizontal practices at issue are not "inherently suspect," participating physicians have considerable latitude, because the practices need pass muster only under a full rule-of-reason analysis. For example, joint buying cooperatives and standardized referral protocols will be condemned only if they have actual anticompetitive effects that outweigh their efficiency-enhancing, procompetitive benefits. And in the usual case, actual anticompetitive effects are unlikely unless the participants collectively possess market power. Thus, a group consisting of only a small portion of the competing practitioners in a market can almost always engage freely in conduct that does not fall into the "inherently suspect" category.

That leads me to the types of "inherently suspect" arrangements that are nevertheless likely to be permissible. First, and perhaps most obviously, competing physicians can lawfully collaborate by fully integrating their practices and finances through the formation of a partnership, joint venture, or other similar arrangement. Through these mechanisms, physicians alter their status as competitors of each other in order to form some greater whole, such as a multi-specialty clinic or group practice. This is precisely the type of arrangement that the Supreme Court characterized favorably in Maricopa. While mergers of physicians' practices are subject to scrutiny under Section 7 of the Clayton Act, mergers involving sufficient numbers of providers to raise substantial competitive concerns are likely to be extremely rare.

Second, providers usually can work together without antitrust difficulties if they form a "network;" that is, a group of providers who are not actual competitors because they practice in different geographical areas or in different specialties. Networks may permit physicians to offer service packages that insurers find appealing. Thus, for example, an insurer that has a statewide contract for public employees might be interested in a network of high quality, cost-conscious podiatrists, chiropractors, optometrists, physical therapists, nurse practitioners, dentists, or even physicians in a particular medical specialty, to provide covered services to employees. While providers in a network may have some minimal competitive overlap, or may be potential competitors of each other, a carefully structured network can usually minimize, if not eliminate, this overlap.[6] Speaking for myself, I would not be concerned about a network where competitive overlap among the participants was marginal and minimal, or where their status as potential competitors was theoretical rather than real.

Third, physicians may be able to collaborate in order to integrate vertically for the purpose of entering a related market, such as the provision of laboratory, x-ray, or pharmacy services, or the sale of durable medical equipment. While antitrust and other concerns potentially could arise from subsequent anticompetitive abuse of such joint ventures, normally their establishment would be viewed as a procompetitive activity in the market, making a new source of such goods or services available to consumers. I think this is what the Supreme Court recognized in *Maricopa* when it observed that neither the physicians nor their foundation for medical care was engaged in the insurance market -- a new product market. Had the physicians entered a new product market, their program probably would have been evaluated under the rule of reason. In fact, this is the position that the Federal Trade Commission formalized in its 1981 Statement of Enforcement Policy With Respect to Physician Agreements to Control Medical Prepayment Plans. The legitimate integration of resources by physicians in establishing and operating such plans, which are in a vertically adjacent product market, requires reliance on a rule-of-reason analysis, under which a plan is likely to be illegal only if its anticompetitive effects outweigh its procompetitive benefits.

I'd like to conclude my remarks by discussing a fourth type of joint activity that is of great interest to many providers and attorneys today: preferred provider organizations ("PPOs"). The crucial question is when and how competing physicians can jointly offer their services as a PPO to insurers, employers, and patients, and jointly decide on the prices at which those services will be offered. Let me tell you how I think such an arrangement might be structured, and the arguments that could support its legality.

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[6] *See, e.g.*, staff advice letter from M. Elizabeth Gee, Assistant Director, Bureau of Competition, to Charles E. Rosolio (May 15, 1987) (re Maryland Medical Eye Associates, P.A.).

The first question is whether the PPO under scrutiny constitutes a true economic integration. In order to ensure that the venture is regarded as a true integration, participating physicians should develop and expand the ways in which they share the financial success or failure of the PPO's programs. The Supreme Court contrasted the deficient arrangement in *Maricopa* to those in which "persons who would otherwise be competitors pool their capital and share the risks of loss as well as the opportunities for profit."[7] The Court did not, however, identify the degree of financial integration needed to satisfy this standard, and no bright line has as yet been defined.

The safest approach would probably be to ensure that the sharing of financial rewards and risks -- whether through capital contribution, profit sharing, fee withholds, or any of a myriad of other ways -- is sufficiently well-established to ensure that the member physicians' mutual incentive to act in the best interests of the PPO outweighs their conflicting incentives as individual practicing physicians. One way to help achieve this degree of financial mutuality is to assure that business from PPO enrollees represents a substantial part of each member physician's practice.

The second step is to identify and emphasize PPO functions that the member physicians could not undertake by themselves. What is it about the PPO that is new, or that provides a different product from the simple provision of medical services by its individual member physicians? The Court in *BMI* observed that the blanket licensing arrangement created a product where "the whole is truly greater than the sum of its parts," and the association was "not really a joint sales agency offering the individual goods of many sellers, but . . . [was] a separate seller offering its blanket license, of which the individual compositions are raw material."[8] The organizers of a truly pro-competitive PPO similarly should be able to show that their group provides medical services more efficiently than individual physicians could. Law firms can make that showing; why not PPOs?

The third step is to establish exactly why an agreement on price is important to the effectiveness of the PPO. As *BMI* indicates, a joint venture can legitimately offer a package deal at a single set of prices. It is crucial to establish, however, that in the market the PPO is intended to serve, the fact that it can offer a package deal at a single set of prices represents a feature of the PPO that prospective buyers find important.

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[7] 457 U.S. at 331.

[8] 441 U.S. at 21-22.

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

December 17, 1980

The Honorable Wendell H. Ford
Chairman, Consumer Subcommittee
Committee on Commerce, Science, and Transportation
Room 130 Russell Office Building
Washington, D.C. 20510

The Honorable John C. Danforth
Ranking Minority Member, Consumer Subcommittee
Committee on Commerce, Science, and Transportation
Room 130 Russell Office Building
Washington, D.C. 20510

Dear Senators Ford and Danforth:

This is in response to your letter of June 13, 1980, concerning one aspect of this agency's jurisdiction over "unfair or deceptive acts or practices." You informed us that the Subcommittee was planning to hold oversight hearings on the concept of "unfairness" as it has been applied to consumer transactions. You further informed us that the views of other interested parties were solicited and compiled in a Committee Print earlier this year.[1] Your letter specifically requested the Commission's views on cases under Section 5 "not involving the content of advertising," and its views as to "whether the Commission's authority should be limited to regulating 'false or deceptive' commercial advertising." Our response addresses these and other questions related to the concept of consumer unfairness.

We are pleased to have this opportunity to discuss the future work of the agency. The subject that you have selected appears to be particularly timely. We recognize that the concept of consumer unfairness is one whose precise meaning is not immediately obvious, and also recognize that this uncertainty has been honestly troublesome for some businesses and some members of the legal profession. This result is understandable in light of the general nature of the statutory standard. At the same time, though, we believe we can respond to legitimate concerns of business and the Bar by attempting to delineate in this letter a concrete framework for future application of the Commission's unfairness authority. We are aided in this process by the cumulative decisions of this agency and the federal courts, which, in our opinion, have brought added clarity to the law. Although the administrative and judicial evolution of the consumer unfairness concept has still left some necessary flexibility in the statute, it is possible to provide a reasonable working sense of the conduct that is covered.

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[1] Unfairness: Views on Unfair Acts and Practices in Violation of the Federal Trade Commission Act (1980) (hereinafter referred to as "Committee Print").

In response to your inquiry we have therefore undertaken a review of the decided cases and rules and have synthesized from them the most important principles of general applicability. Rather than merely reciting the law, we have attempted to provide the Committee with a concrete indication of the manner in which the Commission has enforced, and will continue to enforce, its unfairness mandate. In so doing we intend to address the concerns that have been raised about the meaning of consumer unfairness, and thereby attempt to provide a greater sense of certainty about what the Commission would regard as an unfair act or practice under Section 5.

This letter thus delineates the Commission's views of the boundaries of its consumer unfairness jurisdiction and is subscribed to by each Commissioner. In addition, we are enclosing a companion Commission statement that discusses the ways in which this body of law differs from, and supplements, the prohibition against consumer deception, and then considers and evaluates some specific criticisms that have been made of our enforcement of the law.[2] Since you have indicated a particular interest in the possible application of First Amendment principles to commercial advertising, the companion statement will include discussions relevant to that question. The companion statement is designed to respond to the key questions raised about the unfairness doctrine. However, individual Commissioners may not necessarily endorse particular arguments or particular examples of the Commission's exercise of its unfairness authority contained in the companion statement.

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[2] Neither this letter nor the companion statement addresses ongoing proceedings, but the Commission is prepared to discuss those matters separately at an appropriate time.

Commission Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction

Section 5 of the FTC Act prohibits, in part, "unfair . . . acts or practices in or affecting commerce."[3] This is commonly referred to as the Commission's consumer unfairness jurisdiction. The Commission's jurisdiction over "unfair methods of competition" is not discussed in this letter.[4] Although we cannot give an exhaustive treatment of the law of consumer unfairness in this short statement, some relatively concrete conclusions can nonetheless be drawn.

The present understanding of the unfairness standard is the result of an evolutionary process. The statute was deliberately framed in general terms since Congress recognized the impossibility of drafting a complete list of unfair trade practices that would not quickly become outdated or leave loopholes for easy evasion.[5] The task of identifying unfair trade practices was therefore assigned to the Commission, subject to judicial review,[6] in the expectation that the underlying criteria would evolve and develop over time. As the Supreme Court observed as early as 1931, the ban on unfairness "belongs to that class of phrases which do not admit of precise definition, but the meaning and application of which must be arrived at by what this court elsewhere has called 'the gradual process of judicial inclusion and exclusion.' "[7]

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[3] The operative sentence of Section 5 reads in full as follows: "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful." 15 U.S.C. § 45(a)(1).

[4] In fulfilling its competition or antitrust mission the Commission looks to the purposes, policies, and spirit of the other antitrust laws and the FTC Act to determine whether a practice affecting competition or competitors is unfair. See, e.g., FTC v. Brown Shoe Co., 384 U.S. 316 (1966). In making this determination the Commission is guided by the extensive legislative histories of those statutes and a considerable body of antitrust case law. The agency's jurisdiction over "deceptive acts or practices" is likewise not discussed in this letter.

By 1964 enough cases had been decided to enable the Commission to identify three factors that it considered when applying the prohibition against consumer unfairness. These were: (1) whether the practice injures consumers; (2) whether it violates established public policy; (3) whether it is unethical or unscrupulous.[8] These factors were later quoted with apparent approval by the Supreme Court in the 1972 case of Sperry & Hutchinson.[9] Since then the Commission has continued to refine the standard of unfairness in its cases and rules, and it has now reached a more detailed sense of both the definition and the limits of these criteria.[10]

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[5] *See* H.R. Conf. Rep. No. 1142, 63d Cong., 2d Sess., at 19 (1914) (If Congress "were to adopt the method of definition, it would undertake an endless task"). In 1914 the statute was phrased only in terms of "unfair methods of competition," and the reference to "unfair acts or practices" was not added until the Wheeler-Lea Amendment in 1938. The initial language was still understood as reaching most of the conduct now characterized as consumer unfairness, however, and so the original legislative history remains relevant to the construction of that part of the statute.

[6] The Supreme Court has stated on many occasions that the definition of "unfairness" is ultimately one for judicial determination. *See, e.g., FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 249 (1972); *FTC v. R.F. Keppel & Bro.*, 291 U.S. 304, 314 (1934).

[7] *FTC v. Raladam Co.*, 283 U.S. 643, 648 (1931). *See also FTC v. R.F. Keppel & Bro.*, 291 U.S. 304, 310 (1934) ("Neither the language nor the history of the Act suggests that Congress intended to confine the forbidden methods to fixed and unyielding categories").

[8] The Commission's actual statement of the criteria was as follows:

> (1) whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise -- whether, in other words, it is within at least the penumbra of some common-law, statutory, or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers (or competitors or other businessmen).

Statement of Basis and Purpose, Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324, 8355 (1964).

Consumer injury

Unjustified consumer injury is the primary focus of the FTC Act, and the most important of the three S&H criteria. By itself it can be sufficient to warrant a finding of unfairness. The Commission's ability to rely on an independent criterion of consumer injury is consistent with the intent of the statute, which was to "[make] the consumer who may be injured by an unfair trade practice of equal concern before the law with the merchant injured by the unfair methods of a dishonest competitor."[11]

The independent nature of the consumer injury criterion does not mean that every consumer injury is legally "unfair," however. To justify a finding of unfairness the injury must satisfy three tests. It must be substantial; it must not be outweighed by any countervailing benefits to consumers or competition that the practice produces; and it must be an injury that consumers themselves could not reasonably have avoided.

① ¶ First of all, the injury must be substantial. The Commission is not concerned with trivial or merely speculative harms.[12] In most cases a substantial injury involves monetary harm, as when sellers coerce consumers into purchasing unwanted goods or services[13] or when consumers buy defective goods or services on credit but are unable to assert against the creditor claims or defenses arising from the transaction.[14] Unwarranted health and safety risks may also support a finding of unfairness.[15] Emotional impact and other more subjective types of harm, on the other hand, will not ordinarily make a practice unfair. Thus, for example, the Commission will not seek to ban an advertisement merely because it offends the tastes or social beliefs of some viewers, as has been suggested in some of the comments.[16]

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[9] FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 244-45 n.5 (1972). The Circuit Courts have concluded that this quotation reflected the Supreme Court's own views. See Spiegel, Inc. v. FTC, 540 F.2d 287, 293 n.8 (7th Cir. 1976); Heater v. FTC, 503 F.2d 321, 323 (9th Cir. 1974). The application of these factors to antitrust matters is beyond the scope of this letter.

[10] These standards for unfairness are generally applicable to both advertising and non-advertising cases.

[11] 83 Cong. Rec. 3255 (1938) (remarks of Senator Wheeler).

[12] An injury may be sufficiently substantial, however, if it does a small harm to a large number of people, or if it raises a significant risk of concrete harm.

2 Second, the injury must not be outweighed by any offsetting consumer or competitive benefits that the sales practice also produces. Most business practices entail a mixture of economic and other costs and benefits for purchasers. A seller's failure to present complex technical data on his product may lessen a consumer's ability to choose, for example, but may also reduce the initial price he must pay for the article. The Commission is aware of these tradeoffs and will not find that a practice unfairly injures consumers unless it is injurious in its net effects.[17] The Commission

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[13] *See, e.g., Holland Furnace Co. v. FTC*, 295 F.2d 302 (7th Cir. 1961) (seller's servicemen dismantled home furnaces and then refused to reassemble them until the consumers had agreed to buy services or replacement parts).

[14] Statement of Basis and Purpose, Preservation of Consumers' Claims and Defenses, 40 Fed. Reg. 53506, 53522-23 (1975).

[15] For an example see *Philip Morris, Inc.*, 82 F.T.C. 16 (1973) (respondent had distributed free-sample razor blades in such a way that they could come into the hands of small children) (consent agreement). Of course, if matters involving health and safety are within the primary jurisdiction of some other agency, Commission action might not be appropriate.

[16] *See, e.g.,* comments of Association of National Advertisers, Committee Print at 120. In an extreme case, however, where tangible injury could be clearly demonstrated, emotional effects might possibly be considered as the basis for a finding of unfairness. *Cf.* 15 U.S.C. §§ 1692 *et seq.* (Fair Debt Collection Practices Act) (banning, *e.g.,* harassing late-night telephone calls).

[17] *See Pfizer, Inc.*, 81 F.T.C. 23, 62-63 n.13 (1972); Statement of Basis and Purpose, Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures, 43 Fed. Reg. 59614, 59636 n.95 (1978). When making this determination the Commission may refer to existing public policies for help in ascertaining the existence of consumer injury and the relative weights that should be assigned to various costs and benefits. The role of public policy in unfairness determinations will be discussed more generally below.

also takes account of the various costs that a remedy would entail. These include not only the costs to the parties directly before the agency, but also the burdens on society in general in the form of increased paperwork, increased regulatory burdens on the flow of information, reduced incentives to innovation and capital formation, and similar matters.[18]

③ Finally, the injury must be one which consumers could not reasonably have avoided.[19] Normally we expect the marketplace to be self-correcting, and we rely on consumer choice — the ability of individual consumers to make their own private purchasing decisions without regulatory intervention — to govern the market. We anticipate that consumers will survey the available alternatives, choose those that are most desirable, and avoid those that are inadequate or unsatisfactory. However, it has long been recognized that certain types of sales techniques may prevent consumers from effectively making their own decisions, and that corrective action may then become necessary. Most of the Commission's unfairness matters are brought under these circumstances. They are brought, not to second-guess the wisdom of particular consumer decisions, but rather to halt some form of seller behavior that unreasonably creates or takes advantage of an obstacle to the free exercise of consumer decisionmaking.[20]

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[18] For example, when the Commission promulgated the Holder Rule it anticipated an overall lowering of economic costs to society because the rule gave creditors the incentive to police sellers, thus increasing the likelihood that those selling defective goods or services would either improve their practices or leave the marketplace when they could not obtain financing. These benefits, in the Commission's judgment, outweighed any costs to creditors and sellers occasioned by the rule. *See* Statement of Basis and Purpose, Preservation of Consumers' Claims and Defenses, 40 Fed. Reg. 53506, 53522-23 (1975).

[19] In some senses any injury can be avoided — for example, by hiring independent experts to test all products in advance, or by private legal actions for damages — but these courses may be too expensive to be practicable for individual consumers to pursue.

[20] This emphasis on informed consumer choice has commonly been adopted in other statutes as well. *See, e.g.,* Declaration of Policy, Fair Packaging and Labeling Act, 15 U.S.C. § 1451 ("Informed consumers are essential to the fair and efficient functioning of a free market economy").

Sellers may adopt a number of practices that unjustifiably hinder such free market decisions. Some may withhold or fail to generate critical price or performance data, for example, leaving buyers with insufficient information for informed comparisons.[21] Some may engage in overt coercion, as by dismantling a home appliance for "inspection" and refusing to reassemble it until a service contract is signed.[22] And some may exercise undue influence over highly susceptible classes of purchasers, as by promoting fraudulent "cures" to seriously ill cancer patients.[23] Each of these practices undermines an essential precondition to a free and informed consumer transaction, and, in turn, to a well-functioning market. Each of them is therefore properly banned as an unfair practice under the FTC Act.[24]

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[21] See, e.g., Statement of Basis and Purpose, Labeling and Advertising of Home Insulation, 44 Fed. Reg. 50218, 50222-23 (1979); Statement of Basis and Purpose, Posting of Minimum Octane Numbers on Gasoline Dispensing Pumps, 36 Fed. Reg. 23871, 23882 (1971). See also Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976).

[22] See Holland Furnace Co. v. FTC, 295 F.2d 302 (7th Cir. 1961); cf. Arthur Murray Studio, Inc. v. FTC, 458 F.2d 622 (5th Cir. 1972) (emotional high-pressure sales tactics, using teams of salesmen who refused to let the customer leave the room until a contract was signed). See also Statement of Basis and Purpose, Cooling-Off Period for Door-to-Door Sales, 37 Fed. Reg. 22934, 22937-38 (1972).

[23] See, e.g., Travel King, Inc., 86 F.T.C. 715, 774 (1975). The practices in this case primarily involved deception, but the Commission noted the special susceptibilities of such patients as one reason for banning the ads entirely rather than relying on the remedy of fuller disclosure. The Commission recognizes that "undue influence" in advertising and promotion is difficult to define, and therefore exercises its authority here only with respect to substantial coercive-like practices and significant consumer injury.

[24] These few examples are not exhaustive, but the general direction they illustrate is clear. As the Commission stated in promulgating its Eyeglasses Rule, the inquiry should begin, at least, by asking "whether the acts or practices at issue inhibit the functioning of the competitive market and whether consumers are harmed thereby." Statement of Basis and Purpose, Advertising of Ophthalmic Goods and Services, 43 Fed. Reg. 23992, 24001 (1978).

Violation of public policy

The second S&H standard asks whether the conduct violates public policy as it has been established by statute, common law, industry practice, or otherwise. This criterion may be applied in two different ways. It may be used to test the validity and strength of the evidence of consumer injury, or, less often, it may be cited for a dispositive legislative or judicial determination that such injury is present.

Although public policy was listed by the S&H Court as a separate consideration, it is used most frequently by the Commission as a means of providing additional evidence on the degree of consumer injury caused by specific practices. To be sure, most Commission actions are brought to redress relatively clear-cut injuries, and those determinations are based, in large part, on objective economic analysis. As we have indicated before, the Commission believes that considerable attention should be devoted to the analysis of whether substantial net harm has occurred, not only because that is part of the unfairness test, but also because the focus on injury is the best way to ensure that the Commission acts responsibly and uses its resources wisely. Nonetheless, the Commission wishes to emphasize the importance of examining outside statutory policies and established judicial principles for assistance in helping the agency ascertain whether a particular form of conduct does in fact tend to harm consumers. Thus the agency has referred to First Amendment decisions upholding consumers' rights to receive information, for example, to confirm that restrictions on advertising tend unfairly to hinder the informed exercise of consumer choice.25/

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25. See Statement of Basis and Purpose, Advertising of Ophthalmic Goods and Services, 43 Fed. Reg. 23992, 24001 (1978), citing Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976).

Conversely, statutes or other sources of public policy may affirmatively allow for a practice that the Commission tentatively views as unfair. The existence of such policies will then give the agency reason to reconsider its assessment of whether the practice is actually injurious in its net effects.[26] In other situations there may be no clearly established public policies, or the policies may even be in conflict. While that does not necessarily preclude the Commission from taking action if there is strong evidence of net consumer injury, it does underscore the desirability of carefully examining public policies in all instances.[27] In any event, whenever objective evidence of consumer injury is difficult to obtain, the need to identify and assess all relevant public policies assumes increased importance.

Sometimes public policy will independently support a Commission action. This occurs when the policy is so clear that it will entirely determine the question of consumer injury, so there is little need for separate analysis by the Commission. In these cases the legislature or court, in announcing the policy, has already determined that such injury does exist and thus it need not be expressly proved in each instance. An example

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26. Cf. Statement of Basis and Purpose, Advertising of Ophthalmic Goods and Services, supra; see also n.17 supra.

27. The analysis of external public policies is extremely valuable but not always definitive. The legislative history of Section 5 recognizes that new forms of unfair business practices may arise which, at the time of the Commission's involvement, have not yet been generally proscribed. See page 4, supra. Thus a review of public policies established independently of Commission action may not be conclusive in determining whether the challenged practices should be prohibited or otherwise restricted. At the same time, however, we emphasize the importance of examining public policies, since a thorough analysis can serve as an important check on the overall reasonableness of the Commission's actions.

of this approach arose in a case involving a mail-order firm.[28] There the Commission was persuaded by an analogy to the due-process clause that it was unfair for the firm to bring collection suits in a forum that was unreasonably difficult for the defendants to reach. In a similar case the Commission applied the statutory policies of the Uniform Commercial Code to require that various automobile manufacturers and their distributors refund to their customers any surplus money that was realized after they repossessed and resold their customer's cars.[29] The Commission acts on such a basis only where the public policy is suitable for administrative enforcement by this agency, however. Thus it turned down a petition for a rule to require fuller disclosure of aerosol propellants, reasoning that the subject of fluorocarbon safety was currently under study by other scientific and legislative bodies with more appropriate expertise or jurisdiction over the subject.[30]

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28. Spiegel, Inc. v. FTC, 540 F.2d 287 (7th Cir. 1976). In this case the Commission did inquire into the extent of the resulting consumer injury, but under the rationale involved it presumably need not have done so. See also FTC v. R.F. Keppel & Bro., 291 U.S. 304 (1934) (firm had gained a marketing advantage by selling goods through a lottery technique that violated state gambling policies); cf. Simeon Management Corp., 87 F.T.C. 1184, 1231 (1976), aff'd, 579 F.2d 1137 (9th Cir. 1978) (firm advertised weight-loss program that used a drug which could not itself be advertised under FDA regulations) (alternative ground). Since these public-policy cases are based on legislative determinations, rather than on a judgment within the Commission's area of special economic expertise, it is appropriate that they can reach a relatively wider range of consumer injuries than just those associated with impaired consumer choice.

29. A surplus occurs when a repossessed car is resold for more than the amount owed by the debtor plus the expenses of repossession and resale. The law of 49 states requires that creditors refund surpluses when they occur, but if creditors systematically refuse to honor this obligation, consumers have no practical way to discover that they have been deprived of money to which they are entitled. See Ford Motor Co., 94 F.T.C. 564, 618 (1979) appeal pending, Nos. 79-7649 and 79-7654 (9th Cir.); Ford Motor Co., 93 F.T.C. 402 (1979) (consent decree); General Motors Corp., D. 9074 (Feb., 1980) (consent decree). By these latter two consent agreements the Commission, because of its unfairness jurisdiction, has been able to secure more than $2 million for consumers allegedly deprived of surpluses to which they were entitled.

30. See Letter from John F. Dugan, Acting Secretary, to Action on Smoking and Health (January 13, 1977). See also Letter from Charles A. Tobin, Secretary, to Prof. Page and Mr. Young (September 17, 1973) (denying petition to exercise § 6(b) subpoena powers to obtain consumer complaint information from cosmetic firms and then to transmit the data to FDA for that agency's enforcement purposes).

To the extent that the Commission relies heavily on public policy to support a finding of unfairness, the policy should be clear and well-established. In other words, the policy should be declared or embodied in formal sources such as statutes, judicial decisions, or the Constitution as interpreted by the courts, rather than being ascertained from a general sense of the national values. The policy should likewise be one that is widely shared, and not the isolated decision of a single state or a single court. If these two tests are not met the policy cannot be considered as an "established" public policy for purposes of the S&H criterion. The Commission would then act only on the basis of convincing independent evidence that the practice was distorting the operation of the market and thereby causing unjustified consumer injury.

Unethical or unscrupulous conduct

Finally, the third S&H standard asks whether the conduct was immoral, unethical, oppressive, or unscrupulous. This test was presumably included in order to be sure of reaching all the purposes of the underlying statute, which forbids "unfair" acts or practices. It would therefore allow the Commission to reach conduct that violates generally recognized standards of business ethics. The test has proven, however, to be largely duplicative. Conduct that is truly unethical or unscrupulous will almost always injure consumers or violate public policy as well. The Commission has therefore never relied on the third element of S&H as an independent basis for a finding of unfairness, and it will act in the future only on the basis of the first two.

We hope this letter has given you the information that you require. Please do not hesitate to call if we can be of any further assistance. With best regards,

Michael Pertschuk
Michael Pertschuk
Chairman

Paul R. Dixon
Paul Rand Dixon
Commissioner

David A. Clanton
David A. Clanton
Commissioner

Robert Pitofsky
Robert Pitofsky
Commissioner

Patricia P. Bailey
Patricia P. Bailey
Commissioner

Enclosure

COMPANION STATEMENT ON THE COMMISSION'S CONSUMER UNFAIRNESS JURISDICTION

This statement is intended to supplement the Comission's letter on the consumer unfairness jurisdiction. It will discuss two additional subjects. The first is the manner in which the unfairness jurisdiction relates to and complements the ban against deceptive practices, and the second is a consideration of certain specific criticisms that have been made of the enforcement of the unfairness jurisdiction.[1]

I. The Need for the Prohibition of Unfair Acts or Practices

The Commission's unfairness jurisdiction has become an important part of its ability to protect consumers against certain abusive practices. The unfairness standard supplements, rather than duplicates, other aspects of the FTC Act. The various components of the statute form an integrated whole, allowing the Commission to promote the diverse benefits of a free and open economy. Thus the ban on unfair competition prevents exclusionary or anticompetitive behavior and helps preserve a full variety of marketplace options for consumers to choose among; the ban on deception helps ensure that consumers will not make that choice on the basis of misleading information; and the ban on unfair practices ensures that the choice is not distorted by coercion, the withholding of important information, or similar practices. Safeguards at all three levels are needed to ensure that substantial consumer injury is adequately addressed.

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[1] As before, this statement does not address the Commission's jurisdiction over unfair methods of competition.

There are many ways in which consumer decisions may be distorted or coerced without resort to clear, outright deception. For this reason, the Commission has challenged many practices, including most of those discussed below, as both deceptive and unfair. Elimination of the Commission's unfairness jurisdiction and sole reliance on a deception standard in its stead[2] would at best create ambiguity about the status of such practices and at worst permit significant abuses that the law now clearly prevents. The drawbacks of eliminating the Commission's unfairness jurisdiction are illustrated by the Eyeglasses Rule, which involved several different restraints on consumer choice.[3] The Commission found that many optometrists refused to give customers written copies of their lens prescriptions, so that consumers who received eye examinations from one practitioner were prevented from shopping to buy their eyeglasses from less expensive providers. These restraints were not deceptive, but they often prevented consumers from buying eyeglasses at the lowest possible price. Their combined effect was to inflate artificially the cost of eye care, a burden which fell most heavily on the poor and the elderly. A statute which did not prohibit unfair acts or practices would have made it difficult for the Commission to prevent this injury.

Buyers are sometimes overtly coerced. Some sellers have, for example, pressured consumers into a distraught state of mind, even physically preventing them from leaving the room during the sales presentation, in order to coerce a sale.[4] In other instances, door-to-door salesmen have refused to leave customers' homes until they purchased expensive goods or services.[5] Both of these practices were so coercive that they tended to curtail the free exercise of consumer choice.

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[2] Some suggestions to this effect have appeared in the Committee Print. See, e.g., Comments of General Mills, Inc. (Committee Print at p. 22); Comments of Sears, Roebuck & Co. (Committee Print at p. 139); Comments of the American Retail Federation (Committee Print at p. 156).

[3] Trade Regulation Rule, Advertising of Ophthalmic Goods and Services, 43 Fed. Reg. 23992 (1978). Portions of the rule were later remanded for the Commission to determine whether sellers had changed their practices in light of recent Supreme Court decisions. American Optometric Ass'n v. FTC, 626 F.2d 896 (D.C. Cir. 1980).

[4] Arthur Murray Studio, Inc., 78 F.T.C. 401, 439-41 (1971), aff'd, 458 F.2d 622 (5th Cir. 1972).

Sometimes consumer unfairness is found even without coercion or denials of product information. A striking example arose in the early 1970's when a company began promoting razor blades in a way that risked serious injury to small children. Free samples of the blades were included indiscriminately in advertising supplements to home-delivered newspapers, without any protective packaging that would keep children who found them from injuring themselves. The Commission was able to use its unfairness jurisdiction to negotiate a consent decree barring this unsafe marketing technique.[6] A statute allowing the Commission to move only against deception might have left it less able to protect children against the practice.

Most of the Commission's consumer unfairness actions have historically been directed against techniques other than commercial advertising, since the most serious abuses in advertising have often involved some form of deception and thus could be challenged directly under that portion of the statute. However, the Commission has also encountered injurious advertising practices which ought to be prohibited, and that could most readily be characterized as unfair. Thus the Commission has used its authority over unfair acts and practices to negotiate consent decrees barring advertisements which needlessly depicted young children engaged in unsafe or illegal behavior, thereby creating a danger that other children would be led to imitate what they saw.[7] Also, the Commission has required advertisements to disclose product information that was necessary for consumers to compare the efficiency of competing brands of home insulation[8] and the octane levels of competing brands of gasoline.[9] The absence of this information tended seriously to undercut the ability of consumers to make rational product choices, causing substantial consumer injury.

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[5] See Statement of Basis and Purpose, Cooling-Off Period for Door-to-Door Sales, 37 Fed. Reg. 22934 (1972). Other aspects of this rule, of course, involved deceptive practices. For a litigated case involving the rule see New Rapids Carpet Center, Inc., 90 F.T.C. 64, 119-20 (1977).

[6] Philip Morris, Inc., 82 F.T.C. 16 (1973).

As we have noted before, certain aspects of these practices might be reached under a deception theory, but the issue is unclear and it seems difficult to rely exclusively on deception to reach all instances of coercion, overreaching and inadequate product information disclosure. It might, of course, be theoretically possible to correct these abuses individually, by passing a series of specifically tailored prohibitions without resort to a general statutory ban on unfair acts and practices. This approach has serious drawbacks, however; indeed, it was considered and rejected by Congress nearly seventy years ago when it first enacted Section 5. As the Senate Commerce Committee reasoned then,

> The Committee gave careful consideration to the question as to whether it would attempt to define the many and variable unfair practices which prevail in commerce and to forbid their continuance or whether it would, by a general declaration condemning unfair practices, leave it to the commission to determine what practices were unfair. It concluded that the latter course would be better, for the reason, as stated by one

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[7] E.g., AMF, Inc., C-3011 (1980) (bicycle advertisement showing children riding bicycles in violation of proper highway safety rules); Mego International, 92 F.T.C. 186 (1978) (children playing with electrical appliances near water and without adult supervision); Uncle Ben's, Inc., 89 F.T.C. 131 (1977) (advertisement showing young children cooking on a gas range without adult supervision); General Foods Corp., 86 F.T.C. 831 (1975) (natural-food advocate eating wild nuts and berries).

[8] Trade Regulation Rule, Labeling and Advertising of Home Insulation, 44 Fed. Reg. 50218 (1979).

[9] Trade Regulation Rule, Posting of Minimum Octane Numbers on Gasoline Dispensing Pumps, 36 Fed. Reg. 23871 (1971). The Commission found that it would be more effective to disclose the information at the point of sale than in media advertising, but the principle is the same.

> of the representatives of the Illinois Manufacturers' Association, that there were too many unfair practices to define, and after writing 20 of them into law it would be quite possible to invent others.[10]

In short, the language of "unfairness" has been an integral part of the FTC Act from its beginnings. It represents a considered judgment on the part of Congress and the courts that the Commission can interpret a reasonably flexible statute with sufficient specificity to protect consumers in the context of a continually evolving marketplace. The unfairness standard, in conjunction with the rule against deception, is necessary to enable the Commission to address the full range of business practices that result in substantial injury to consumers and distortion of the marketplace.

II. Specific Criticisms of the Consumer Unfairness Authority

Notwithstanding the general development of the FTC's consumer unfairness authority as described above, some specific questions have been raised about its application to particular circumstances. A number of these have been collected in the Committee Print, "Views on Unfair Acts and Practices in Violation of the Federal Trade Commission Act." There appear to be three major questions. These express concern that the unfairness authority: (1) is an overbroad delegation of discretionary authority which allows the Commission to restrict practices that cause no consumer injury; (2) fails to give adequate notice of what conduct will be considered unfair; and (3) may violate the First Amendment when applied to commercial speech. Each of these points will be considered in turn.

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[10] S. Rep. No. 597, 63d Cong., 2d Sess. 13 (1914). See also H.R. Rep. No. 1142, 63d Cong., 2d Sess. 19 (1914) ("It is also practically impossible to define unfair practices so that the definition will fit business of every sort in every part of this country. Whether competition is unfair or not generally depends upon the surrounding circumstances of the particular case.")

Agency discretion and consumer injury

The discussion in our letter on the limits to the Commission's unfairness jurisdiction will, we hope, allay concerns that the agency might find practices to be unfair in the absence of consumer injury, or that its unfairness jurisdiction leaves too much to its discretion. As stated therein, the presence of unjustified consumer injury — whether shown by objective evidence, by clear public policy, or both — is essential to a determination that particular conduct is unfair. Similarly, the discussion should indicate that the bounds of the Commission's discretion under its unfairness jurisdiction have been clarified and limited.

In addition to the definable limits on unfairness as described in the Commission's letter, there are also external procedural checks which ensure that the agency does not overstep the bounds of intended congressional delegation. Industry-wide rules are subject to formal congressional review under the terms of recent amendments to the Federal Trade Commission Act.[11] Further, all Commission rules and orders are subject to judicial review.[12] Professor Kenneth Culp Davis, a leading authorit[illegible]n administrative law, has concluded that safeguards of this type provide a more meaningful check on agency discretion than would actions to prescribe more specific standards.[13]

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[11] *See* FTC Improvements Act of 1980, Pub. L. 96-252, § 21.

[12] *See, e.g., FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 249 (1972); *FTC v. R.F. Keppel & Bro.*, 291 U.S. 304, 314 (1934).

[13] *See* K. DAVIS, ADMINISTRATIVE LAW TREATISE, § 2.00-3, at 47 (1970 Supp.). For this reason statutes that imply a similar degree of discretion in other agencies have been regularly upheld. *See, e.g., National Broadcasting Co. v. United States*, 319 U.S. 190 (1943) (upholding FCC's reliance on its power to license broadcasting stations in "the public interest, convenience, or necessity" as authority for issuing regulations concerning contractual relations between broadcasters and networks); *Permian Basin Area Rate Cases*, 390 U.S. 747 (1968) (upholding the Federal Power Commission's area rate fixing regulations under the statutory power to determine whether independent producers of natural gas have rates that are "just and reasonable"). While these other agencies may have a more specific subject matter under their jurisdiction, within that jurisdiction they have a degree of discretion that is not unlike the FTC's.

Congressional and judicial review of agency determinations of unfairness will, moreover, contribute to the continual process of more precisely defining the proper scope of the Commission's unfairness jurisdiction.

Adequacy of notice

A second concern is that the statutory term "unfair" is too imprecise to give businesses adequate notice of what conduct will be considered improper. To the extent that this concern rests on questions about the scope of agency discretion, these issues have been addressed above. To the extent that this concern also rests upon perceptions of procedural unfairness, the Commission would like to bring to the committee's attention procedural protections that currently exist in both its adjudicative and rulemaking proceedings.

Under the Federal Trade Commission Act, businesses cannot be subjected to sanctions for engaging in an unfair practice until the practice has been defined with specificity in a full-dress adjudication or rulemaking.[14] If, in an adjudication, a firm is found to have engaged in a newly identified unfair act or practice, civil penalties are not assessed; rather, the remedies are limited to preventing the firm from engaging in the same or related practices in the future,[15] and, in appropriate cases, to providing relief for injured parties. Only if the order is violated may penalties then be assessed.[16]

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[14] See 15 U.S.C. §§ 45(b), 57a.

[15] 15 U.S.C. § 45(b). See FTC v. Colgate-Palmolive Co., 380 U.S. 374, 394-95 (1965); FTC v. National Lead, 352 U.S. 419, 429 (1957); FTC v. Ruberoid Co., 343 U.S. 470, 473 (1952); Joseph Siegel Co. v. FTC, 327 U.S. 608, 612-13 (1946).

[16] See 15 U.S.C. § 45(l).

There are also some special provisions for immediate consumer redress, but these apply only to conduct that "a reasonable man would have known under the circumstances was dishonest or fraudulent," and that determination must be made in federal court.[17]

The situation in rulemaking is similar. The Commission's rulemaking authority was clarified and its powers to enforce its rules through the assessment of civil penalties were expanded in 1975, with the passage of the Magnuson Moss Federal Trade Commission Improvements Act. However, in granting the Commission this new authority, Congress also imposed procedural requirements on the rulemaking process that significantly exceed the protections that the Administrative Procedures Act affords participants in the proceedings of other agencies.[18] For example, participants in Magnuson Moss rulemakings have the right to conduct cross examination on disputed issues of material fact, to present oral testimony to the Commission, and to offer rebuttal evidence at various stages of the proceeding.[19] More recently Congress provided additional procedural protections to participants in FTC rulemakings. For example, the Commission is required to publish an "advance notice of proposed rulemaking" to obtain public input in the initial stages of a Commission inquiry, even before any particular rule provisions are proposed.[20] In addition, the Commission must issue a preliminary regulatory analysis weighing projected costs and benefits of any proposed rule and a final regulatory analysis when promulgating a final rule.[21] Finally, firms that are unsure whether certain activities are legally unfair are at all times invited to seek advisory opinions from the staff.

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17. See 15 U.S.C. § 57b(a).

18. See 5 U.S.C. § 551 et seq.

19. See 15 U.S.C. § 57a(c).

20. See FTC Improvements Act of 1980, Pub. L. 96-252 (May 28, 1980) § 8, 15 U.S.C. § 57a(b).

21. Id. at § 15, 15 U.S.C. § 57b-3.

First Amendment considerations

A third concern is that the First Amendment forbids the regulation of "unfair" but nondeceptive advertisements since these are essentially a form of protected commercial speech.[22] The Commission agrees that the First Amendment imposes stringent limitations upon the extent to which the government may regulate nondeceptive commerical speech, but further believes that the First Amendment does not entirely preclude such regulation.[23] Far from constituting a reason for eliminating the Commission's unfairness jurisdiction as it pertains to advertising, the First Amendment protections accorded commercial speech constitute a strong argument against the need for legislative modification of the unfairness mandate, since they already ensure that the unfairness clause may be applied to advertising only under limited circumstances.

Supreme Court decisions on commercial speech have made clear that deceptive commercial speech, and commercial speech that advocates an illegal activity, are entitled to no constitutional protections.[24] By contrast, commercial speech that neither deceives consumers nor advocates illegal conduct is entitled to substantial constitutional protection.[25] The extent of such protection was articulated by the Supreme Court in the recent case of *Central Hudson Gas and Electric Corp. v. Public*

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[22] This objection pertains to the Commission's unfairness authority only as it relates to advertising. The Commission's principal past uses of unfairness have occurred with respect to sales practices that did not involve commerical speech.

[23] *Central Hudson Gas and Electric Corp. v. Public Service Comm'n*, 100 S.Ct. 2343, 2351 (1980).

[24] *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 (1976); *Central Hudson supra*, 100 S.Ct. at 2351.

[25] The Supreme Court has, however, upheld prophylactic measures designed to prevent serious risks of deception or coercion. In *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 462 (1978), for example, the Court upheld a rule against in-person solicitation of clients by lawyers, suggesting that such rules could be valid even without specific findings that deception or coercion had actually occurred. *See also Friedman v. Rogers*, 99 S.Ct. 887, 896 (1979) (regulating conduct found to create "a significant possibility" of deception).

Service Comm'n.[26] At issue in that case was a state regulation prohibiting public utilities from advertising to promote the increased use of electricity. The majority found that such commercial speech was entitled to some constitutional protection because it was not misleading and did not relate to unlawful activity. However, it then determined that such speech could still be regulated by the government consistently with the First Amendment provided that three criteria were met. First, the government must assert a substantial interest to be served by its regulation of commercial speech. Second, the restriction must directly advance the stated governmental interest. Finally, the restriction may not be more extensive than necessary.[27] The Supreme Court has thus generally described the boundaries of the government's authority to limit commercial speech that does not mislead or encourage illegal activity.

In the past the Commission has made sparing use of its unfairness authority to regulate commercial speech.[28] To the extent that it may need to exercise such authority in the future, it will do so in conformity with the standards established in Central Hudson. Moreover, the Commission recognizes that commercial speech questions involve a developing area of constitutional law. For example, Central Hudson did not define precisely when a governmental interest will be deemed substantial. Furthermore, the case involved state regulations and thus the considerations applied to the Commission's mandate to eliminate unfair practices may not be precisely the same.[29] The Commission will therefore proceed with caution as the courts continue to refine the standards for governmental regulation of nondeceptive commercial speech.

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[26] 100 S.Ct. 2343 (1980).

[27] 100 S.Ct. at 2351.

[28] Indeed, in the Eyeglasses Rule the Commission used its unfairness authority to free commercial advertising from unjustified restrictions.

[29] Even apart from constitutional considerations, the Commission's need to consider consumer injury and public policy before determining whether a practice is unfair means that it has less freedom to take many of the regulatory actions that are open to the states.

III. Conclusion

In short, three things may be said about the Commission's consumer unfairness jurisdiction. First, the Commission has sought to construe its jurisdiction in limited, specific, and market-oriented terms. Second, the Commission may be less able to reach many instances of significant consumer harm if its jurisdiction is limited to "deception." Third, the Commission has attempted to define its unfairness jurisdiction with sufficient particularity to answer criticisms that the law is excessively uncertain or is invoked in circumstances that threaten freedom of speech.

By direction of the Commission.

Carol M. Thomas
Secretary

DATED: December 17, 1980

REPORT ON LITIGATION
TO THE
HOUSE OF DELEGATES, AMERICAN MEDICAL ASSOCIATION

Delivered by Newton N. Minow
Chicago, Illinois
December 3, 1978

Delegates, Officers, and Guests of the American Medical Association --

I am honored to be here today at the invitation of Dr. Hunter and Dr. Rial and to report to you on the status of the litigation in which the American Medical Association is a party. I will describe briefly the legal actions in which the Association is involved and explain the reasoning behind the positions that the Association is taking in each case.

Our firm, Sidley & Austin, was first retained by the AMA in 1974. Since that time, we have been carrying out the Association's determined effort to maintain individual freedom and independence in the practice of medicine as a learned and noble profession. The first case in which we represented the Association, for example, raised the question of whether the Department of Health, Education and Welfare could lawfully promulgate regulations which unduly interfered with the exercise of physicians' professional judgments regarding the hospitalization of patients. As many of you will recall, we succeeded in having those regulations struck down by a federal district court which was affirmed by a Court of Appeals. You will be interested to know that in June of this year, the government published an announcement in the Federal Register finally conceding that these regulations were unlawful.

We live in a time of increasing governmental intervention in the delivery of medical care. Your Association has, therefore, increasingly taken to the courts to limit bureaucratic interference with the practice of medicine and governmental disregard for the rights of patients and the physicians who serve them. The AMA's efforts in this area have continued during the past year.

Last spring, the Secretary of Health, Education and Welfare announced his intention to publish a list of all physicians who treated Medicare beneficiaries in 1977 and to attribute to each physician the amount of income that he or she allegedly had received in Medicare payments. The only justification that the Secretary has offered for this invasion of privacy is that publication of this information might stimulate debate on the costs of health care. Representatives of this Association pointed out to Secretary Califano that this goal could be achieved equally well — but without interfering with anyone's privacy — by not identifying individual physicians or simply by breaking down expenditures by medical procedure rather than by provider. Yet the Secretary refused to compromise.

Consequently, your Association took the matter last June to federal court in Chicago. We were successful in obtaining a court order preventing the proposed publication of the information. At the suggestion of the Judge, we then intervened in a pre-existing case in Jacksonville, Florida in which another court had granted a similar request in a suit previously filed by the Florida Medical Association. This fall the United States District Court in Jacksonville issued a writ of injunction restraining publication of any of the information on the proposed list. Despite the determined efforts of the government to have this injunction lifted, I can report to you that HEW is still enjoined from publishing the list. A battle on this issue lies ahead, and I assure you that we will continue to make every effort to see that it is never published.

At just about the same time that HEW indicated that it would publish the list of the Medicare-related incomes of identified physicians, the Federal Trade Commission promulgated a Trade Regulation Rule entitled "Advertising of Ophthalmic Goods and Services". Among other things, this Rule would invalidate all state laws governing the advertising and dispensing of ophthalmic goods and services which the Commission deems unfair. The Rule has direct and immediate ramifications for ophthalmologists. Of great significance, the Rule would, if upheld by the courts, establish the astonishing authority of the Federal Trade Commission to override the laws and policy decisions of state legislatures in medical matters whenever the Commission considers these decisions unfair. It could serve as a precedent which might lead the Commission to try to strike down other state laws such as those regulating medical licensure, medical discipline, and medical practice. Thus, the Ophthalmic Goods Rule poses a threat to the practice of medicine which far transcends its immediate terms.

Your Association has therefore challenged the Federal Trade Commission by turning to the courts. Along with nine sovereign states and the American Optometric Association, we sought review of the Ophthalmic Goods Rule in the United States Court of Appeals in Washington. Our brief was filed in October, and the states filed theirs in November. The brief of the Commission is due this month. If the Court adheres to its customary time schedule, the case will be heard in late spring, and a decision will follow sometime late 1979 or 1980. I think it likely that this case will ultimately reach the Supreme Court.

Your Association is also resisting efforts by the Federal Trade Commission to remove it from the process of accreditation of medical schools. In an unprecedented move, the Commission appeared before the United States Office of Education last year to urge that the Liaison Commission on Medical Education not be recertified as the official accrediting agency for medical education. It argued that because some of the members of the LCME were appointed by the AMA, the LCME could not be counted upon to make impartial decisions on matters of accreditation. The notion that a professional association should not be involved in such matters is of course reprehensible. The AMA was founded to improve the quality of medical education and has worked continuously for over a century to effectuate this goal. Accordingly, both your Association and the LCME strongly opposed the position that the FTC took before the Office of Education. After a hearing and a review of past performance, the LCME was provisionally recertified for two years as the officially recognized accrediting agency for medical schools. That battle will again be fought next year.

Undaunted, the Federal Trade Commission launched its own investigation of alleged efforts by the AMA to restrict the number of physicians graduating from medical school. That investigation has now been pending for over a year. A formal complaint has not as yet been issued. Interestingly, the Commission's staff person with primary responsibility for health matters recently was quoted in the press as saying that the AMA may not have restricted entry into medical schools after all. The facts may be getting through.

In another area, the facts have not been getting through. I turn now to the attack brought by the Federal Trade Commission on the Association's ethical standards. In 1975, the FTC issued, without any prior notice or investigation, a complaint challenging the ethical principles applicable to advertising and solicitation by physicians. The FTC also attacked the ethical guidelines applicable to a variety of contractual arrangements entered into by physicians — for example, the ethics of a partnership between a physician and a lay person.

When this proceeding was instituted in December of 1975, we attempted to settle the case. We hoped to settle for two reasons. First, we knew that it would be difficult to find a less favorable forum for resolution of the issues raised by the case than the Federal Trade Commission. We feared that we would not get a fair, unbiased proceeding because the Commission had already displayed its hostility to organized medicine. Furthermore, the administrative law judge assigned to the case had been for many years a prosecutor for the Commission. Finally, we knew that, incredible as it might seem to a non-lawyer, we would have to appeal the initial decision of the administrative law judge to the full Federal Trade Commission — the very people who directed the complaint in the first instance.

Indeed, just last month, all four members of a panel reporting to the National Commission for the Review of Antitrust Laws and Procedures recommended that the FTC's antitrust litigation responsibilities be terminated or significantly modified. As panel member Professor Glen Weston of George Washington Law School observed, the majority of Administrative Law Judges have served as FTC prosecuting lawyers. Moreover, there is also the problem that three of the five commissioners had no significant training in antitrust law before their appointments.

Our second reason for seeking to settle was that since the case would involve the production of thousands of documents and scores of witnesses from around the country, we knew that it would be exceedingly costly. The investigation of each document and the preparation of each witness is a difficult, time-consuming, and costly task. So we hoped to be able to save the Association the enormous expense that the case would inevitably entail.

But the staff of the Commission flatly rejected our position that professional associations, including the AMA, have not only the right but the responsibility and duty to see that advertising by their members is limited to truthful, objective, verifiable information that will help enable patients to make an informed choice among physicians. Instead, the Commission insisted that the AMA and state and local medical societies should play absolutely no role in setting standards of ethical promotional practices by their members. The staff insisted that advertising by physicians should be regulated exclusively by the government. This was a position that neither you nor we could accept. For it is premised on the proposition that professional men and women cannot be trusted to regulate themselves in the public interest. And that proposition is fundamentally inconsistent with the Association's basic principles.

The decision of the Administrative Law Judge was announced this week. After reading it, I submit that George Orwell's 1984 has arrived six years early. The world of Big Brother, seeking to take over the independent, professional practice of medicine, has arrived in 1978.

I wish there were time to undertake an extensive legal analysis of the decision. I will limit this to a summary of our arguments and the manner in which they were resolved.

First, the FTC has jurisdiction only over persons, partnerships, and for-profit corporations. Since the AMA is clearly not a person or a partnership, the question is whether it is organized for the profit of itself or its members. We demonstrated that the vast majority of the Association's activity is devoted to scientific, educational, and public health matters. The Judge, however, chose to discount this evidence and to find that the AMA is organized for the profit of its members because it has done such things as offer its members a retirement plan and oppose enactment of certain forms of national health insurance.

Second, we argued that the AMA should be judged on its current ethical positions, not on the basis of statements from the 1930s, 40s, 50s and 60s made in a vastly different legal and social climate. The Judge absolutely refused to accept this argument and virtually ignored the 1977 edition of the Opinions and Reports of the Judicial Council.

We pointed out that questions of ethics are local matters which arise locally and are resolved locally. We demonstrated that state and local medical societies are autonomous organizations which make decisions independently of the AMA. Apparently ignoring this evidence, the Judge found that there is a grand conspiracy among the AMA and state and local medical societies to stifle all advertising and subvert any innovative form of health care delivery.

I could go on and on and on, but the Opinion is 312 pages, single-spaced. The one positive note is that this Order is not a final one. It still must go before the full Federal Trade Commission, the United States Court of Appeals, and possibly the Supreme Court before it becomes final. While we are not optimistic about the results before the FTC, we are hopeful that we shall find justice when we have our day in the federal courts. We will not rest until this misguided decision — so contrary to the public interest and so alien to our basic American traditions of freedom — is overturned.

I say that because I believe that the Initial Decision of the Administrative Law Judge is a direct assault on the entire concept of professionalism and will, if allowed to stand, lead to the deception and injury of thousands upon thousands of innocent patients.

The Order entered by the Administrative Law Judge would forbid the AMA and its constituent and component medical societies from involving themselves in any way in the advertising, promotional practices, or contractual arrangements of physicians. Thus, if an AMA member were to make misleading claims about his or her skill or fees, the medical societies would be powerless even to advise the physician of the problem or to declare the advertising unethical. All that they could do would be to complain to Big Brother — in the form of the FTC.

It must be asked: How could this Administrative Law Judge have reached these results? The short answer is that he distorted or ignored much of the evidence and most of the applicable law.

In our defense of the case, we offered witnesses who had literally been mutilated after responding to misleading advertisements and high pressure tactics of certain advertising physicians. We have testimony from the mother of a woman who died as a result of an abdominoplasty performed by an advertising physician after several other physicians had advised the patient that she was unacceptable risk for surgery. On the witness stand, these patients begged medical societies to do something to prevent the fraud and incompetence to which they had fallen victim. Now a Federal Trade Commission employee has said that the medical profession is prohibited by law from doing anyting to regulate this kind of behavior. And it is equally forbidden to take any action against those within its ranks who advertise the worst sort of abortion mills, who claim that they will guarantee a weight loss of 20 pounds within two weeks, and who make other statements which lead patients to choose physicians on the basis of who is the best advertiser rather than who is the best physician.

As outrageous as this is, there is another aspect of the Administrative Law Judge's Order which is even more sweeping. And that is this: The AMA may not even establish ethical guidelines governing the advertising and solicitation practices of its members unless it first obtains "the permission and approval of the Federal Trade Commission". This provision has staggering implications for the First Amendment, the traditions of professionalism, and ethical standards which have always been basic values in our society. This provision would mean that federal officials in Washington, and not the profession itself, would determine what constitutes ethical behavior by physicians.

I am reminded of the poem "The Second Coming" by William Butler Yeats. In that poem, Yeats said, "The best lack all conviction/While the worst are full of passionate intensity". In its misguided zeal, the Federal Trade Commission has been full of passionate intensity. But we as professionals must never lose the courage of our convictions. We will do everything we can to seek reversal of this attempt to put the independent practice of medicine in the hands of government.

In the cases discussed thus far, our adversary has been an agency of the federal government. I turn now to another set of cases in which the Association is involved. Here, our opponent is not the government but a number of individual chiropractors. These chiropractors have brought actions against the AMA and several other defendants in three different forums — federal court in Philadelphia, state court in New Jersey, and federal court in Chicago.

All three of these actions have several features in common. Each is brought under antitrust laws which declare it unlawful for two or more persons to combine or conspire to restrain competition. Plaintiffs in each case contend that by declaring it unethical to associate professionally with unscientific practitioners, physicians have combined to prevent chiropractors from competing within the limits of their licenses. More specifically, plaintiffs in each case take the position that physicians have conspired to restrain competition by uniformly denying chiropractors access to the use of diagnostic procedures that they require in order to practice within the scope of their license.

At the same time, the three actions differ from one another in some respects. The Pennsylvania and New Jersey cases are each brought by local chiropractors concerned with local conditions. The Chicago case, by contrast, is brought by chiropractors from different parts of the United States. They appear to be concered primarily with the effect of various medical society positions on chiropractic as a whole. Thus, the relief they seek is infinitely more sweeping than that sought by plaintiffs in Pennsylvania and New Jersey. They have asked, for example, for millions of dollars in damages and for one million dollars for each of the next ten years to establish and operate a research institute for the advancement of chiropractic.

Finally, the three cases have this in common: The defense of each lawsuit has required a heavy financial outlay by this Assocation, which because of its size and public visibility is inevitably viewed as the principal defendant. The expenditure of resources that has occurred until now will be dwarfed by the expenses that will be incurred if the cases go to trial. Moreover, any adverse decision against the AMA in a litigated case will in all likelihood provoke treble damages lawsuits against the Association and against state and local medical societies by chiropractors throughout the country.

In view of the costs and risks of these lawsuits, we believe that the most responsible course is to explore settlement on reasonable terms -- just as we would explore settlement of any case of this nature. In fact, as you know, a tentative settlement agreement has been reached by the Association in the Philadelphia case. Under the terms of this tentative settlement, the AMA acknowledges simply that each individual physician must decide for him or herself whether and in what circumstances to accept referrals from a chiropractor. It acknowledges that chiropractors are licensed limited practitioners as that term is used in the Opinions and Reports of the Judicial Council.

The Association is represented by a different local law firm in each of these chiropractic cases. Our firm has acted in an overview advisory capacity to the AMA in these suits. We have carefully reviewed the tentative settlement in light of the applicable law. On the basis of this review, we conclude that this settlement is a reasonable one and is in the best interests of the Association. Our opinion on this matter is shared by the able Philadelphia law firm which represents the Association in this case on a day-to-day basis.

Four specialty societies and some individual physicians, however, disagree with our assessment. Representatives of these societies feel so strongly about this subject that they have taken legal steps to try to prevent finalization of the settlement. While we respect their views, our own independent judgment differs from their opinion.

As we understand it, the position of these specialty societies is based on three concerns. First, the societies believe that an acknowledgement that chiropractors are licensed limited practitioners would give chiropractic legitimacy as a healing art. Second, they fear that settlement of the Philadelphia case would have an adverse effect on the defense of the Chicago case. Third, they contend that the tentative settlement would violate Principle 3 of the Principles of Medical Ethics, which provides that a physician shall not "associate professionally" with anyone who practices a method of healing not founded on a scientific basis. These are very important and deeply felt concerns, all of which deserve respect — and answers.

First, in acknowledging that chiropractors are licensed limited practitioners, the settlement merely recognizes the fact that chiropractors have been licensed under the law of every state to perform certain limited procedures prescribed by state law. Much as we might wish it otherwise, the state legislatures in all fifty states have already considered chiropractors as licensed limited practitioners. The tentative settlement in no way changes the legal status of chiropractors.

Moreover, it is basic to understand that the settlement terms agreed upon by the AMA in no way obligate any physician to have any contact whatsoever with any chiropractor. If an individual physician considers chiropractors to be unscientific cultists, as far as the AMA is concerned that physician need never accept a referral from a chiropractor. Indeed, anyone who sought to force a physician to treat patients sent by a chiropractor, be it the government, a hospital board, or a group of individuals, would be acting contrary to the AMA position.

Second, both in our judgment and that of the lawyers representing the Association in Philadelphia and in Chicago, the settlement does not jeopardize the defense of the Chicago case. It does not in any way constitute an admission that the AMA has violated the law. In fact, it makes no statement about legal liability. What it does do is make clear that the AMA's position is that it is up to the individual physician to decide whether or in what circumstances to accept patients sent by chiropractors. If anything, therefore, the settlement helps our defense in Chicago because this position is far easier to defend under the antitrust laws than is a blanket prohibition on accepting referrals in any circumstances. Moreover, the tentative settlement removes the possibility of an adverse ruling in the Philadelphia case. In this connection, we are of the opinion that your Board of Trustees has appropriate authority to settle lawsuits when it believes that settlement is in the best interest of the Association.

Third, the settlement is, in our judgment, consistent with the prohibition in the Principles of Medical Ethics against associating professionally with an unscientific practitioner. The Judicial Council's interpretation of this prohibition declares it unethical for a physician to enter a course of treatment jointly with an unscientific practitioner. It does not interpret the Principles to forbid accepting a referral from such an individual and thereafter dealing with the patient exclusively. As I read the Principles as interpreted by the Judicial Council, the tentative settlement is in complete accord with the Association's policy that a physician may accept a referral from an unscientific practitioner as long as the physician doesn't undertake a course of treatment together with such practitioner.

Under ordinary circumstances, a speaker's platform is not the best place for a lawyer to give advice to a client. But the circumstances facing the AMA today are not ordinary. I will therefore briefly discuss some of the antitrust implications of the chiropractic litigation.

Supreme court

Although the Sherman Antitrust Act was enacted in 1890, it was not until *Goldfarb v. Virginia State Bar Association*, *et al*. was decided in 1975 that the Supreme Court first declared that there was no "learned profession" exclusion from application of the Act. As a result, physicians, lawyers -- all professionals -- are now subject to the Sherman Act. Under this Act and analagous state statutes, a concerted refusal to have anything to do with certain providers of goods or services, under threat of disciplinary action, is a violation of law.

Neither this House nor the Judicial Council has ever stated that a physician may not individually decide to accept as his or her patient a person sent for treatment or diagnosis by a chiropractor. As a matter of fact, if the AMA or any other medical organization threatened to discipline for unethical conduct members who accept patients referred by chiropractors, regardless of circumstance, that organization would be in direct violation of the Sherman Antitrust Act.

Chiropractic as a system of treating all disease by spinal manipulation or adjustment was described by the AMA House of Delegates in 1966 as an "unscientific cult" and a "hazard to rational health care". The AMA is clearly within its "first amendment" rights when it continues to express its concern about the danger of unscientific methods of treatment. But it should not take a position which would make it unethical for a member to decide individually to accept as a patient a person referred by a chiropractor.

As you know, Section 4 of the Principles of Medical Ethics requires physicians to "observe all laws". Judicial Council Opinion 3.70 is consistent with the law and reflects the long-standing position of the AMA both prior to the Goldfarb decision in 1975 and since. We are unaware of a single instance in which a surgeon has been disciplined by the AMA or any medical society for performing surgery on a patient referred by a chiropractor. Nor are we aware of any radiologist or other physician who has been censored or admonished for accepting for treatment or diagnostic services a patient sent by a chiropractor. This Association should not now adopt a position contrary to law and contrary to its own ethics which require that physicians observe the law.

You are committed to improving people's health through scientific medicine. I share your outrage when innocent patients are exposed to unscientific practices contrary to their best interests. You who are devoted to the welfare of the patient must be appalled when state legislatures permit a system of treatment which runs directly contrary to this goal. But your concern for the patient and for quality care cannot lead you into positions that violate the law -- in this case, the antitrust laws -- no matter how well-intentioned those positions are.

* * *

In June of 1977, the Chairman of the Federal Trade Commission said: "The Federal Trade Commission is not a health or medical agency. To paraphrase a President who was hardly our patron saint, Calvin Coolidge, 'The business of the FTC is business.' And we recognize, along with most Americans, that the delivery of heatlh care is business, an industry of vast proportions and vital effect. Health Care has become our business. I have no apologies for that; in fact, one might ask: 'What took the FTC this long?'"

As men and women trained in a noble and learned profession, you are now on notice that parts of our government claim that the medical profession is not a profession but a business — and that health care is now the FTC's business. At a time when the President and many members of Congress are saying that our country is over-regulated, the FTC wants to regulate the practice of medicine. I read you one ominous sentence from the decision of the FTC Administrative Law Judge: "Respondents will be permitted to participate in setting ethical guidelines for the conduct of their members after first obtaining permission and approval of the Federal Trade Commission."

1984 has arrived in 1978. You, the members of an ancient and honored profession, are not even to participate in setting your own ethical standards without first getting the permission and approval of the federal government. I don't have to tell you how much is at stake here, fundamental principles far beyond this particular case.

I serve in another cause with Dallin H. Oaks, President of Brigham Young University, who is also a leader of the American Association of Independent Colleges and Universities. President Oaks said a few months ago: "I contend that government authorities need to be just as careful about regulating schools, colleges, and universities as they are about interferences with newspapers, public meetings or any other delivery mechanism for the products of free speech. As the essential transmitters of our culture and as the source, teacher, and practitioner of values in our society, schools, colleges and universities must be assured a wide range of freedom for their activities of discovery, advocacy, and practice."

The same observation is true with respect to the practice of medicine. The freedom to practice medicine is at stake, not only for yourselves, but for your patients and for future physicians and future patients. It is essential that all of you remain united to preserve your freedom — and the freedom of your patients. I am proud to carry on the battle to maintain professionalism, for it is a just one.

In accepting the Nobel Prize for literature, William Faulkner declared, "I believe that man will not merely endure: He will prevail." In acting as counsel to this great Association, I share Faulkner's faith. I believe that as long as it stands together, the medical profession will not merely endure. It will prevail.

ELIOT L. ENGEL, NEW YORK
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MEMORANDUM

DATE: MARCH 27, 1989

TO: CHAIRMAN RON WYDEN

FROM: SUBCOMMITTEE STAFF

SUBJECT: UNQUALIFIED DOCTORS PERFORMING COSMETIC SURGERY: MUST THE "BUYER BEWARE" IN THIS MULTI-BILLION DOLLAR MEDICAL INDUSTRY?

Mr. Chairman, over the last two years, under your leadership the staff has investigated many trends in the medical field and how they are affecting the quality and cost of health care. No trend is more pronounced and widespread than that of more and more doctors operating outside the hospital setting. Although we have found that most in the medical community are honest and ethical, many are not. Whether it be consumers counting on safe, reliable medical testing, infertile couples seeking to have a baby or those seeing lumps and bumps in the mirror, all are highly susceptible to potential exploitation.

The common thread through all the subcommittee's investigations has been (1) inappropriate use and lack of credentials, (2) misuse of medical technologies, (3) no minimum standards for outpatient facilities and (4) false or misleading advertising. Unfortunately, we also found that the government has either been oblivious to these alarming trends or they have chosen to ignore them. The government has abdicated its responsibility, the quality of health care has deteriorated and American consumers has been left to fend for themselves.

No where is this more evident than in the ugly realities of the multi-billion dollar cosmetic surgery industry.

COSMETIC SURGERY BOOM: MEDICINE GOES MADISON AVENUE

Over the last several years, many patients of cosmetic surgery have been seriously injured and some have died following elective cosmetic procedures. It appears that the field is being overrun by less than fully qualified doctors operating with little or no oversight by either government or their peers.

Fully 95 percent of all cosmetic surgery procedures are now done outside of hospitals, in doctors' offices or in limited service clinics.

Based on the staff's six-month investigation, it appears that the government has become an unwitting accomplice by making consistently uninformed and ill-conceived decisions on how to guarantee safe, affordable medical care. The Federal Trade Commission stands alone in having taken one dramatic -- and many say disastrous -- step that has crippled the medical profession and left the American consumer virtually defenseless.

The FTC declared war on the learned professions as it implemented the Federal Trade Commission Improvement Act of 1975. Advertising came to the legal profession -- followed shortly by the medical profession. It first brought "ambulance chasers" into our living rooms during prime time. According to some doctors and lawyers alike, this single act may be a major contributor to our current malpractice crisis.

Then came the medical profession. With its federal court victory over the AMA and two Connecticut medical organizations, the FTC threw open the regulatory door for medical advertising. Not only did it send the message that the FTC would not prohibit the peddling of medicine, it made it virtually impossible for the medical profession to police its own to ensure ethical standards and quality care.

That history shows that the FTC miscalculated badly and dangerously when it opened up medicine to the kind of advertising previously reserved for the ABCs -- automobiles, beer and cigarettes. The only difference is that in doctors' ads, the Surgeon General's warning is missing.

Until then, the medical profession had managed to limit the old "snake oil" salesman approach to medicine. To curb that 19th Century style of false and deceptive advertising, doctors formed societies, established medical specialties and tested and certified members to boards formally recognized by the American Medical Association.

Now, the barn door has swung open and the quacks have waddled out. History has begun to repeat itself.

This should come as no surprise to the FTC. The agency actually anticipated and accepted that there would be serious risks to patients. As one FTC staffer said,

> "I won't deny the fact that some people will go into brain surgery and have consequences that we all don't want. There will be costs -- really serious costs -- but the benefits are that we will know what the hell is going on in the medical marketplace."

The FTC was right. We do know much more about the medical marketplace. We know that most patients take at face value cosmetic surgeons' ads. We know that they think most cosmetic surgery is safe. We know that they think it's safe to have surgery done in doctors' offices, not just in hospitals. We know that they aren't as careful selecting a doctor because they've been led to believe that virtually anyone can do these "simple" procedures and they can do them virtually anywhere. We know that thanks advertising pandering to underestandable interest in our society's preoccupation with youth hundreds of thousands of Americans are having dozens of these procedures. And finally, we know that the FTC's medical marketplace has become a multi-billion dollar industry in the cosmetic surgery field alone.

Unfortunately, we also know that countless patients are being injured. They are being physically and emotionally scarred and they are being financially drained.

Even when potential patients try to be "good medical consumers," they run into a stone wall erected by state and federal governments, medical societies and individual doctors themselves. With a lot of help from the FTC and some in the medical profession, it has become virtually impossible for patients to tell who is a good, qualified doctor and who is not.

And the marked trend toward outpatient surgery has removed the last vestige of accountability for many doctors. No hospital review board verifies the quality of these surgeons' work. No one guarantees whether the "operating room" has even basic life support equipment. No one ensures that the doctor has good, qualified staff to give anesthetic, to monitor the patient and to respond quickly should complications arise.

The frightening result may be that the new back alley of medicine has become the doctor's office itself. We have found that, incredibly, any doctor who manages to graduate from medical school, and receive a state license, can do anything, be anything. Anyone with a medical degree and a state license can do brain surgery, face lifts, breast reductions or enlargements--even open heart surgery.

This situation exists in every state in the country. But many believe such an environment is far from ethical. Competition has, indeed, come to the medical profession.

WHO'S WHO IN MEDICINE?

Over the years, the "Good Housekeeping Seal of Approval" in medicine has been board certification in a given specialty or area of expertise. But that distinction is murky in cosmetic surgery.

A consumer used to be able to count on a "board certified" doctor having the following qualifications:

- four years of post-graduate medical school;
- three to seven years residency training;
- an unrestricted license to practice; and
- passing a comprehensive medical specialty examination.

But in cosmetic surgery, nearly all boards claim to offer expertise in some procedures. The AMA's American Board of Medical Specialties has approved 23 such boards -- including several claiming to be qualified to do various cosmetic surgery procedures. Thanks to the FTC, however, anyone and any group can create a board, call itself anything and issue certificates suitable for framing. So far, 102 of these self-designated boards have sprung up.

The public is legitimately confused. Not only are individual doctors vying for the public's confidence -- and dollars. Boards themselves engage in what Supreme Court Justice Potter Stewart called "an unseemly rivalry which would enlarge the opportunities of the least scrupulous."

Millions of dollars are spent each year by plastic surgeons, otolaryngologists (ear, nose and throat specialists), eye surgeons and others to convince the public that they are the best. Inter-specialty rivalry has doctors grasping for the golden ring of cosmetic surgery. MacDonalds, Burger King and Wendy's have nothing over these desperate doctors -- many of whom feel that they can't afford not to advertise. Virtually all of them take credit for inventing and perfecting each procedures. And all of them proclaim that the bottom line is patient safety.

"BRAND X" OR "GRADE A"? -- ANATOMY OF AN AD

In an effort to see whether the nation was being blanketed with false, deceptive and misleading advertising, the staff collected and reviewed thousands of sample ads. The Congressional Research Service surveyed six major city magazines for the year 1988, specifically at the subcommittee's request. The subcommittee also analyzed yellow page advertisements for eight other metropolitan markets. Additionally, newspaper ads were reviewed on a random basis.

That review suggests that what had become a way of life for the people of Rodeo Drive in Beverly Hills, has migrated to Main Street, U.S.A. We found the Madison Avenue approach to medical care. The staff has concluded that the field of cosmetic surgery is practicing "Yellow Page Professionalism."

After interviewing numerous doctors from many specialties, lawyers and consumers, the subcommittee staff believes that ads which state, lead one to conclude and purposely omit information are attempting to mislead the consumer. The staff believes that such advertising falls clearly within the jurisdiction of the FTC and should be reviewed by the Commission for appropriate legal action.

The staff has identified the following type of cosmetic surgery ads that should send a red warning flag up to the consumer and the FTC. Advertisements that:

- contain promises about the physical results of surgery;
- contain statements about the surgical procedure;
- contain claims about the innovative character of an operation;
- contain false claims about the physician or his or her staff;
- contain so-called "before and after" photographs, with the "after" photograph posed in a more favorable angle and lighting;
- show the results of one patient's experience or one person's testimonial to apparently imply and mislead other people to conclude that anyone having the same operation can and should have similar results;

- utilize truthful information in a manner that may mislead potential patients as to the qualifications of the advertising physician. An example is one physician who included his membership in the AMA as part of his qualifications. Membership in the AMA is not a function of professional skill;
- assert that a physician is a qualified as a "board certified cosmetic surgeon" when no board of that title is recognized by the American Board of Medical Specialties;
- claim board certification when they are actually certified in other specialties having little or nothing to do with the cosmetic surgery procedures being performed;
- advertise credentials, perhaps impressive to lay persons but medically meaningless, including authorship of articles published in obscure medical journals;
- state doctor inventions of surgical instruments;
- state special residency training and expertise;
- claim state-of-the-art facilities and invite visits by patients who want to make comparisons. Most potential patients have no way to judge its adequacy and medical necessity, and often are mislead by the "Tokyo effect" of fancy gadgets with lights, bells and whistles to suggest safety and state-of-the-art technology;
- lure people into an office by providing something free. The staff believes such ads lead to "hard sell" techniques used once the patient arrives in the office;
- emphasize the reasonableness of fees and the easy financing that's available;
- utilize photographs of attractive models who in most cases have little or no relationship to any cosmetic surgery actually performed on on the model. The staff believes that psychologically appealing advertising appears to minimize the potential health risks of these surgical procedures; and
- fail to mention even the name of the operating surgeon.

WHO'S WATCHING THE STORE?

> "Freedom of speech doesn't give a person the right to yell "fire" in crowded theater, Supreme Court Justice Oliver Wendell Holmes Jr. once noted. Nor should it give con artists the right to promote health frauds through ads in print or on the air. Yet, health fraud lives and even thrives, in no small part because of successful advertising."

One would hope that this warning would be the primer for FTC attorneys charged with protecting the public from false, deceptive and misleading ads -- and the resulting risk to their health. Instead, that quote from "Critiquing Quack Ads" is from a Food and Drug Administration advisory to consumers.

The FTC is still no where to be seen. FDA Commissioner Frank Young told this subcommittee just last week that medical quackery is alive, well and thriving, estimating the costs to consumers at between $10 billion and $40 billion per year. Apparently his agency -- which has little control over false advertising -- is more aware, more concerned and more aggressively trying to protect the public than the FTC -- with its virtually unlimited authority to prohibit such exploitation.

PURPOSE OF SUBCOMMITTEE HEARINGS

Some say the issue is quality. Some say it's dollars and cents. Some say it's a complicated turf battle pitting one medical specialty against another. In any case, the FTC is merely sticking its bureaucratic head in the sand, leaving the hapless medical consumers to fend for themselves. Witnesses before the subcommittee's first hearing on April 4, will include victims of botched cosmetic surgery and representatives from the medical community. Witnesses at the second hearing, on May 2, will include the FTC, the FDA, officials from state licensing and quality assurance boards and medical accrediting societies.

The Voice Of The Quack

Quackery thrives. It thrives because people want to believe there are simple cures for their ills and easy ways to correct their imperfections. The quack understands this and exploits it. His advertisements, as this article points out, are a mixture of mysticism, pseudoscience, and sensationalism.

by Roger W. Miller

The voice of the quack is not a harmless honk. It is a voice that attempts to soothe, to assure the sick, the aging, or the foolish. What the voice really wants is to charm the money out of anyone—whether sick, growing old, or just plain hopeful.

Too often the quack succeeds, and Americans throw away hundreds of millions of dollars annually for a variety of products that can't possibly work. The money flows so fast that Federal and State investigators can't keep pace with all the quack operations.

To an uninvolved observer, the quack's voice may give itself away, the advertisements being parodies of themselves. Even in printed ads, the voice is shrill, though it may not sound that way to the person who is seeking help for real or imagined illnesses or shortcomings.

How does the quack manipulate the language so as to make the shrill sound melodious? A study of quack advertisements in some large circulation newspapers and magazines shows that the language of quackery is quite universal, almost as if every ad writer had taken the same correspondence course in Creative Quackery Ad Writing 101.

Such language often hints at the mystical. But unlike his Medicine Man predecessor, who invoked "nature" or the occult, today's quack is more likely to cloak his claims of knowledge about the unknowable in polysyllabic terms that, to the unwary, sound like major scientific milestones. Thus, "***an amazing breakthrough in medical technology***" has resulted in a product that "***reverses hereditary pattern baldness.***" Or "***clinical studies prove that***" you really can stop the aging process. What's more "***researchers have uncovered the secret that revolutionizes the science of breast development.***"

In the good old days, the typical source of a cure-all potion was supposedly some Indian chief who spent his time digging strange roots rather than scalping white men, or a venerable patriarch in a foreign land who never left his high mountain village because he could maintain perpetual youth or health or both by just swilling his elixir. Today's Medicine Man is not above using the exotic in his promotion pieces. Indeed, sometimes he even combines the foreign with the scientific, as in "***Now from Europe comes a remarkable skin care breakthrough: cell therapy.***" However, instead of an Indian chief or a guru, the ads today are more likely to tout the "***discovery of an Olympic champion.***"

Sharing top billing with science in the get-well-quick ad business is Ma Nature herself. Whether taken orally, rubbed on, played with, or simply looked at, the quack products today are all "***natural.***" They're natural as in "***100 percent natural ingredients***" and "***works safe and naturally***" and "***Nature wants you to function perfectly.***"

But if Mother Nature and scientists are working feverishly to restore your health or youth, your diet is what's killing you, as these lines attest:

"***Modern diets are poor in nutrition.***"

"***Modern food processing strips away many key nutrients from our diets.***"

"***Most people do not manage to eat a well balanced diet.***"

To hear these ad writers talk, we should all be 7-foot-

Quack Language From A to Z

A = Amazing (as in "*amazing* breakthrough")
B = Breakthrough
C = Clinical
D = Discovery, doctor (as in "*Doctor* makes amazing *discovery*.")
E = Exciting, European, enzymes (as in "This *exciting European* discovery of new *enzymes* resulted from an amazing clinical breakthrough.")
F = Fantastic (as in "It was *fantastic*; within 3 weeks the pain had left," writes Mrs. Z. B. of Chatsworth, Calif.); also, formula, fast-working
G = Guaranteed
H = Home cure (as in "Now there's an amazing *home cure* for arthritis, thanks to a fantastic scientific breakthrough accomplished in a Finnish laboratory.")
I = Instant, immediate, inexpensive, ingredient
J = Just (as in "The pain was gone in *just* 3 weeks," reports B. Z. of Bellflower, Ill.)
K = Know-how (as in "With a special brand of understanding and *know-how*, Dr. Strange was able to come up with this secret formula.")
L = Lose (as in "guaranteed to *lose* 3 pounds a night while you sleep.")
M = Medical (also medically approved, medical technology); also miracle and miraculous
N = Natural (as in "Now there's a *natural* way to lose those excess pounds."), may also be used in the French form *naturel*; also nutrients (as in "Your normal diet doesn't provide the proper *nutrients*.")
O = On the spot (as in "Feel the texture of your hair change *on the spot* to silken smoothness.")
P = Painless
Q = Quick
R = Research, researcher, revolutionize (as in "*revolutionize* the process of preventing baldness"); also remarkable (as in "———— is a *remarkable* scientific discovery.")
S = Secret, speed, safe
T = Technology
U = Uncover (as in "researchers *uncover* secret formula")
V = Vanish (as in "liver spots *vanish* miraculously")
W = Wonder, works (as in "It really *works*.")
X = X rays (as in "*X rays* prove that arthritic calcium deposits are cleared up.")
Y = Youthful
Z = Zinc (as in "the mineral crucial to man's prowess.")

ers rather than the nearly 6-footers that we are (or the 5-footers of not too many generations ago who subsisted on nonprocessed foods).

In addition to being scientifically based and natural, such products are always ***fast working***, ***inexpensive***, ***painless***, and ***gurranteed***. Speed is important. The items have to go to work instantly or even sooner. (Some are believed to start working as soon as the buyer writes the check for them—a not too preposterous idea since the one reasonable defense left to a quack is that his product may work because his customers *think* it works.)

Inexpensiveness is a relative word. Quack items often run in the $9.95 range. That may seem like a lot for a package of tea that will provide "***natural prostate rejuvenation***" (as if the prostate had a known function), but $9.95 is less than the cost of a visit to a doctor's office (where the prospective quackery victim would be told only that the prostate has nothing to do with sexual ability).

The products are typically promoted as being painless, although the annals of more than one court will show that some of these products have done physical harm to people. The real harm comes, however, because people rely on the quack's product when they probably should be seeing a physician.

The guarantees may be stated clearly enough. But most people who are made fools of don't like to admit it, even to get their money back.

The quack ad writers often display a little scientific knowledge to explain the wonders their products perform. But the explanations don't go very far. One, for a skin cream, reads: "***Basically, the process involves the use of cell cultures derived from embryonic tissues.***" Sometimes, the language is couched so as to deepen the mystery: "***Apparently what happens is*** . . . ."

The similarity in language in the ads is, to use a favorite word of the quacks, ***amazing***. Words other than amazing that repeatedly find their way out of a quack's mouth and into his advertisements are: ***breakthrough***, ***secret formula***, ***natural***, ***discovery***, ***instant*** or ***instantly***, ***safe***, ***painless***, ***medical***, ***clinical***, and ***research*** or ***researcher***. Several of them may hook right together, like railroad cars. Try it.

Also similar in language are the testimonials from "***satisfied***" users of the products. "***It really works!***" is the most often used testimonial. The speed at which the "***secret formulas***" work is also worthy of comment by Mrs. Satisfied and Mr. Convinced User.

Such is the language of quackery. Oozing with confidence. Friendly, willing to share a secret. Knowledgeable about the maladies of mankind.

But the dulcet tones are dangerous, a siren's song. Watch that friendly arm that drapes over your shoulder; it will lift your billfold when it is withdrawn.

Roger W. Miller is editor of FDA CONSUMER.

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**DEPARTMENT OF HEALTH AND
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Public Health Service
Food and Drug Administration
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Rockville, Md. 20857
Office of Public Affairs**

Quackery Targets Teens

Quackery, an age-old business, costs Americans billions of dollars each year and immeasurable losses suffered from harmful products and delayed medical treatment. The quack's victims are usually thought of as the aged or chronically ill.

But quacks are quick to spot new markets, so it's not surprising that they have discovered teenagers. These youths and their impatience with the blossoming process are fertile ground for quacks. Teenagers are ready to experiment with products that promise to speed their development and ease growing pains.

And many of these junior and senior high school age children have money enough to do the experimenting. In fact, a study by Teenage Research Unlimited revealed that 29 million teenagers spent an average of $80 a month on personal items in 1985 for a total of nearly $28 billion.

Teenagers, anxious to speed their development, are fertile ground for quacks.

Further, in families in which both parents work, teens take on more of the family shopping responsibilities. The U.S. Labor Department reports that as of March 1986, 65 percent of families with teenagers had two working parents. And a 1987 report by Teen Research Unlimited showed that teens do the shopping in 70 percent of households with working mothers.

These young shoppers often have access to mom or pop's credit card. And, like their parents, they are buying more through the mail, a medium that offers a cloak of anonymity under which quacks thrive.

The teen years are often insecure years, filled with questions like: "Am I beautiful (or handsome)?" "Will my breasts ever develop?" "Shouldn't I be more muscular?" "Am I too fat?" "Would a tan give me more sex appeal?"

Quacks love such questions. And they're ready with answers that have been—according to them—"overlooked or ignored by the established scientific community."

Time is of such essence to the young that they grasp at straws and don't recognize the quack's deceptions for what they really are.

Take a look at some of the advertisements in teen magazines. There's a "space age diet" that allows you to "eat all day and still lose weight," a beauty cream that

There is no device or system of exercise that will increase the size of the breasts.

One expert says that as many as three-fourths of high school girls are on a diet at any one time.

will ensure "gorgeous, proportioned breasts," and a pill to provide a tan overnight. Sound unlikely? Impossible is a better word. But, fond of superlatives and driven by desire, teenagers are ready to believe such ads.

Here are some of the dubious products that teenagers today are asked to believe in:

BREAST DEVELOPERS

For decades, millions of dollars have been spent on devices, creams and lotions advertised as breast developers. All wasted. There is no device or system of exercise that will increase the size of the breasts. At best, devices promoted as breast developers merely strengthen and develop the muscles that support the breasts, and exercising these muscles will not appreciably increase breast size.

Creams and lotions advertised as breast developers don't work either. Some contain the hormone estrogen. Estrogen can increase breast size, but in order to be sold without a prescription these products must contain such a small amount of the hormone that its effect is insignificant. (Estrogen is used in birth control pills and to treat symptoms of menopause. FDA approval for estrogen does not include use for breast development.)

The only proven method of increasing breast size is breast augmentation surgery, which carries some risks and is hardly recommended for teenagers.

WEIGHT LOSS

Teenagers—especially girls—are not exempt from the American penchant for dieting. One expert says that as many as three-fourths of high school girls are on a diet at any one time. Writing in the May-June 1987 issue of *Nutrition Today*, Dr. Kelly Brownell of the University of Pennsylvania School of Medicine said that some children begin dieting as early as the fourth grade.

Those figures may startle some people, but not the quacks. They know them well and have pounced on that audience, offering "magical" diets and pills to keep the pounds off. Most of the diets and virtually all of the pills are worthless; some are even dangerous. At times, some diets will achieve a temporary weight loss that is usually unrelated to the "magical" food or pill.

The dieting craze may be particularly questionable for adolescents, since a well-balanced diet is vital during the teen years when the body goes through dramatic change and growth.

Depending on the ingredients, some pills promoted for weight loss can cause side effects such as nervousness, nausea and insomnia, and can also be addictive.

The recognized active ingredient in most nonprescription diet pills is either phenylpropanolamine (PPA) or benzocaine. The effectiveness of these two ingredients for weight loss has yet to be determined by FDA. However, too much PPA has been associated with elevated blood pressure. Benzocaine is supposed to work by numbing the inside of the mouth to make food less appetizing.

Most weight-loss products sold as part of a diet-and-pill plan are harmless. The products don't work, but the plan may. Of course, the plan would work just as well without the product, which is nothing more than a psychological crutch.

Some devices are also promoted for weight loss. Electrical muscle stimulators, for example, have a legitimate use for physical therapy treatment, but FDA has had to take a number of such devices off the market because they were promoted for weight loss and "body toning." These stimulators can be dangerous when used incorrectly. Hazards include electrical shocks and burns.

Body wraps are another favorite gimmick of the quacks. They're touted as a means of "burning fat." The wraps are worn around part or all of the body, sometimes preceded by the application of a cream or lotion. Temporary weight loss may occur as the result of sweating and loss of water in the tissues, but when the water content of the tissue returns to normal, the "lost" weight reappears. The wraps do not "burn" or dissolve fat. Furthermore, experts consider them dangerous because they can cause severe dehydration and circulatory problems.

There are no magic foods, pills, wraps, diets or wands for losing weight. The only way to lose weight is to consistently eat fewer calories than the body needs and uses. But teenagers should be cautioned about excessive dieting. Their growing bodies can't tolerate the nutrient loss that comes with eating too little.

Steroids may well build muscle, but their use can also stunt growth, lead to cancer, ruin the liver, and cause other complications.

STEROIDS AND GROWTH HORMONE

Quackery. That is the bane of sports medicine. We've rid ourselves of some of the worst but there are still many people handing out get-good-quick pills, touting medicines that send blue sparks and make big muscles, or advising athletes to drink superduper seaweed extracts.
—Dr. Daniel F. Hanley, Bowdoin College, Brunswick, Maine, as quoted in *Death in the Locker Room*.

Our sports-loving nation loves a winner, and it's fair to say that most of the 5 million boys and girls who compete in high school sports love to win. Some of them will go to great lengths to do so. That may mean using performance-enhancing drugs such as anabolic steroids and human growth hormone.

Anabolic steroids—compounds similar to the male hormone testosterone—are too often used by athletes, both boys and girls, to build muscle. They are also used by young men who just want to look better. They are prescription drugs, but most of those who use them obtain them illegally, often from the black market. Steroids have a lot of unwanted side effects—that's why they are supposed to be sold only by prescription. They may well build muscle, but it's a losing proposition, because their use—particularly in the large doses that athletes take—can stunt growth, lead to cancer, ruin the liver, and bring on other complications, including enlarged breasts in boys. For girls, the side effects include developing masculine traits that may be irreversible.

Black-market steroids often are produced in another country or by clandestine domestic manufacturers under questionable conditions and may be contaminated. The quacks have also moved in with phony steroids and phony pills that they say—falsely—will counter some of the side effects of steroids.

Earlier this year, FDA warned that a counterfeit version of the hormone human chorionic gonadotropin, or HCG, was being sold to weight lifters and other athletes. The bogus hormones were contaminated with a substance that causes infections and fever.

A black market has also sprung up for human growth hormone. This prescription drug is legitimately given to children who suffer from pituitary dwarfism or growth hormone deficiency, but it, too, has dangerous side effects. Nevertheless, athletes seeking to benefit from added growth are buying the hormone on the black market. Quacks are also marketing "growth tablets" that, in fact, contain no hormones or any other ingredients that can promote growth.

TANNING AND TANNING PILLS

Tanning is never harmless, regardless of the source: the sun, a sunlamp, a tanning bed, or a pill. Exposure to ultraviolet radiation from the sun or other sources leads to premature aging of the skin. It is also the number one cause of skin cancer.

Many teenagers get their tans at tanning parlors, where they may be told that the type of ultraviolet radiation from the lamps will not be harmful. That's not true. Ultraviolet radiation from *any* source can be harmful.

Other youths may turn to tanning pills. But they're not safe either. They generally contain a color additive that has not been approved by FDA for coloring the body. Advertisements claim that the pills produce "a rich, golden-bronze, natural-looking tan" that makes one look "healthy, energetic, and attractive" all year. But the pills actually produce a distinct orange tinge on the skin. The pills may also leave fatty deposits in the blood, liver and skin, and on the eye's retina, where they may interfere with night vision. Further, the "tan" the pills produce is no protection against sunburn.

HAIR: REMOVAL AND GROWTH

The only effective way to remove hair permanently is with electrolysis—a process by which hair roots are destroyed with an electrified needle. Electrolysis should only be performed by a physician or professional electrologist, according to the American Medical Association (AMA). While it is safe when done correctly, it can be tedious, painful and expensive, the AMA adds. Scarring may result and regrowth is possible.

Effective means of temporarily removing hair include *shaving*, *tweezing*, *waxing*, and using *cream* or *lotion* depilatories. But FDA cautions that there is no risk-free method of removing hair. Waxing, for example, can be painful, and creams can cause rashes and swelling.

There is limited good news about removing hair, however. According to the AMA, hair removal does not make renewed growth thicker or stiffer, nor does it quicken regrowth.

While girls struggle to remove hair, some teenage boys worry that they won't be able to keep theirs. Since most baldness is hereditary, young men may take a look at their long-since bald fathers and fear that they will soon be watching the tops of their heads get smoother. There's currently no solution to this dilemma, a fact that bothers quacks not at all. The health fraud artists are ready with a variety of "cures" for baldness, and their intended victims include those worried youngsters.

The would-be hair restorers are trafficking these days in a drug that has shown some ability to stimulate hair growth. That drug is minoxidil, which is used to treat high blood pressure. Publicity about the prescription drug's link to hair growth has laid just enough groundwork for the quacks to capitalize on. However, minoxidil has yet to be approved by FDA for growing hair. So there remains no product available that will grow hair, despite quack ads to the contrary.

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Rockville MD 20857

"LOOK-ALIKE" DRUGS

The widespread use of illegal drugs among teenagers has helped generate a market for "fake" drugs. These "look-alike" drugs are intentionally made to look like amphetamines, barbiturates, or other often-abused drugs. They are sold on the street and by mail order, and the seller often implies that they are the illegal drugs they resemble.

The look-alikes generally contain decongestants, caffeine, and other stimulants in what FDA has called "dangerous, illogical combinations." Some contain alarmingly high doses of one ingredient. When taken in excess or mixed with alcohol, the look-alikes have caused strokes and death. They are extremely dangerous when mixed with, or replaced by, real "uppers" or "downers."

The availability and use of look-alikes make it harder for health professionals and law enforcement officials to combat the problem of illegal drug use. The AMA points out the following problems caused by look-alikes:

- School children and others who don't normally abuse drugs are told that the "look-alikes" are okay to use because they are legal and safe (in fact, they are neither).
- Look-alike drugs may make youngsters believe that the illegal drugs they mimic aren't as potent and dangerous as they really are.
- Traditional drug abuse education programs are hampered by the wide availability of the imitation drugs.
- Physicians and poison centers are deceived by the fake drugs, which makes drug-related diagnoses difficult.
- The look-alikes make it even more difficult for law enforcement officials to stop illegal drug traffic.

Most states have banned the manufacture and marketing of look-alikes, and the federal government has taken action against some manufacturers. But the availability of look-alike drugs is still a threat to the health and safety of teenagers.

RECOGNIZING QUACKERY

It is during the teenage years that people start to become serious consumers, and there's no better time to learn how to avoid quackery. Here are some tips:

- Be wary if immediate, effortless or guaranteed results are promised.
- Look for telltale words and phrases such as "breakthrough," "miracle," "secret remedy," "exclusive," and "clinical studies prove that . . . ."
- Beware of promotions for a single product claimed to be effective for a wide variety of ailments.
- Don't forget that, unlike scientists and health professionals, quacks do not subject their products to the scrutiny of scientific research. The quack simply thrusts a product onto the market in order to get your money.
- Be cautious of money-back guarantees, for a guarantee is only as good as the company that backs it.
- If it sounds too good to be true—it probably is. ■

This article was prepared jointly by FDA and the Council of Better Business Bureaus.

For More Information

If you have questions about a product or company, get answers before you make a purchase. For information, contact:

- the Better Business Bureau
- the nearest Food and Drug Administration office
- your local consumer office or state attorney general's office
- your doctor.

Critiquing Quack Ads

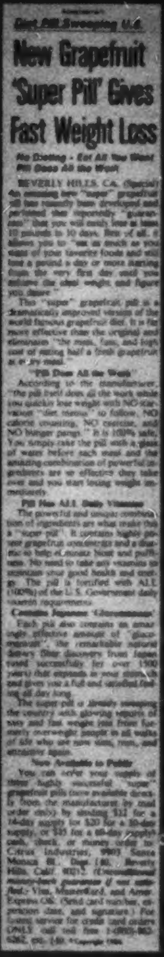
by Roger W. Miller

Freedom of speech doesn't give a person the right to shout "fire" in a crowded theater, Supreme Court Justice Oliver Wendell Holmes Jr. once noted. Nor should it give con artists the right to promote health frauds through ads in print or on the air. Yet, health fraud lives and even thrives, in no small part because of successful advertising.

To get an idea of the prevalence of advertising for possibly fraudulent health items, the Food and Drug Administration contracted with a clipping service to survey the nation's newspapers and magazines for one month. The clipping service came up with a total of 435 questionable ads in publications ranging from the smallest of weekly newspapers to multimillion-circulation magazines.

The 435 ads hardly indicate the true volume of dubious advertising during that period. With more than 10,000 daily and weekly newspapers and general-circulation magazines in the country, any clipping service asked to do a nationwide search is only going to be fractionally successful. However, the clippings give a

Claimed Anti-Aging Formula
PROCAINE H3 THER
The Famous Exotic Diet Pill
"Slim-Caps" Is Finally
Available In The U.S.A.!



Advertisement

Diet Pill Sweeping U.S.

New Grapefruit 'Super Pill' Gives Fast Weight Loss

No Dieting - Eat All You Want Pill Does All the Work

BEVERLY HILLS, CA. (Special) An amazing new "super" grapefruit pill has recently been developed and perfected that reportedly "guarantees" that you will easily lose at least 10 pounds in 10 days. Best of all, it allows you to "eat as much as you want of your favorite foods and still lose a pound a day or more starting from the very first day until you achieve the ideal weight and figure you desire."

This "super" grapefruit pill is a dramatically improved version of the world famous grapefruit diet. It is far more effective than the original and eliminates "the mess, fuss, and high cost of eating half a fresh grapefruit at every meal."

"Pill Does All the Work"

According to the manufacturer, "the pill itself does all the work while you quickly lose weight with NO starvation "diet menus" to follow, NO calorie counting, NO exercise, and NO hunger pangs." It is 100% safe. You simply take the pill with a glass of water before each meal and the amazing combination of powerful ingredients are so effective they take over and you start losing weight immediately.

Pill Has ALL Daily Vitamins

The powerful and unique combination of ingredients are what make this a "super pill". It contains highly potent grapefruit concentrate and a diuretic to help eliminate bloat and puffiness. No need to take any vitamins to maintain your good health and energy. The pill is fortified with ALL (100%) of the U.S. Government daily vitamin requirements.

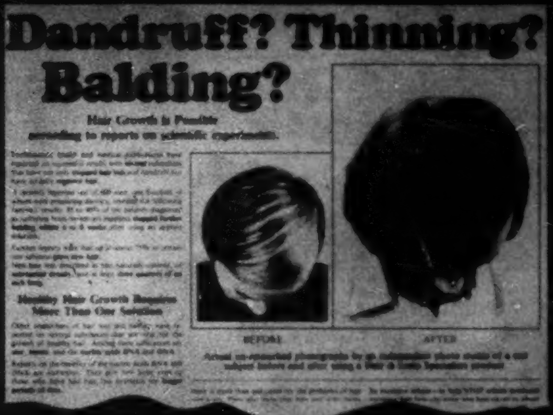
Contains Japanese 'Glucomannan'

Each pill also contains an amazingly effective amount of "glucomannan", the remarkable natural dietary fiber discovery from Japan (used successfully for over 1500 years) that expands in your stomach and gives you a full and satisfied feeling all day long.

The super pill is already sweeping the country with glowing reports of easy and fast weight loss from formerly overweight people in all walks of life who are now slim, trim, and attractive again.

Now Available to Public

You can order your supply of these highly successful "super" grapefruit pills (now available directly from the manufacturer by mail order only) by sending $12 for a 14-day supply (or $20 for a 30-day supply, or $35 for a 60-day supply) cash, check, or money order to: Citrus Industries, 9903 Santa Monica Bl., Dept. 180, Beverly Hills, Calif. 90212. (Unconditional money-back guarantee if not satisfied.) Visa, MasterCard, and Amer. Express OK. (Send card number, expiration date, and signature.) For fastest service for credit card orders ONLY call toll free 1-(800)-862-6262, ext. 180. ©Copyright [illegible]



Dandruff? Thinning? Balding?

Hair Growth is Possible according to reports on scientific experiments.

Healthy Hair Growth Requires More Than One Solution

BEFORE

AFTER

Lose 4-6 inches of bulging fat BEFORE we cash your check!

Let Us Take The Risk!

Don't Hold Fat In... Lose It!

THE NEIGHBORHOOD

After just one day on the Block and Tackle Weight Loss Program, Sybil couldn't be more pleased.

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good idea of what's being peddled to the gullible, the desperate, the people looking for something-too-good-to-be-true.

FDA has been taking steps to discourage fraudulent product advertising and sales. In a joint program with the U.S. Council of Better Business Bureaus, the agency sent information packages to many of the nation's newspapers and magazines and to all radio and TV stations. The material gave tips on how to spot quack ads and offered the services of local FDA and BBB offices to answer questions about the suitability of advertising copy submitted for publication.

In addition, FDA has launched a sort of advertising program of its own. A section called "Health Fraud Notices" has been added to the agency's weekly *Enforcement Report*. The report, a subscription publication made available to the media, lists product recalls, seizures, and other regulatory actions. Now it is being used to warn consumers of current fraudulent products. The first Health Fraud Notice, in the Dec. 12 issue of the publication, labeled as "gross deceptions" waist wraps, vibrating belts and sauna suits advertised to help lose weight. The *Enforcement Report* named the products and the marketers. They are: Shrink Wrap System, Cell-U-Loss Body Toner, and Space Suit Slenderizing Systems, all marketed by three firms: Maximum Exposure Advertising Inc., Stamford, Conn.; Body Shoppe Inc., Ronkonkoma, N.Y.; and New Body Boutique Inc., Bohemia, N.Y. Also named was the Touch-and-Stay-Trimmer by J.M. Devrey Inc., Freeport, N.Y.

There is no scientific or clinical evidence to support the use of body wraps or sauna suits for controlling weight. Nor is there any data to back up promoters' claims that these products will eliminate cellulite and bulging fat, or make "spot reductions" possible, or improve the "calorie burn rate," or control appetite. Accordingly, there are no FDA-approved body wraps or sauna suits.

FDA had previously notified the body wrap companies that their products' labels were false and misleading and that they had failed to register or list their products with FDA as required by law. Listings in the *Enforcement Report* will not necessarily be the end to FDA dealings with these quacks, as the agency will still be free to use regulatory or legal actions in the cases.

Weight-loss products such as body wraps are by far the most popular items being promoted by the fraud artists, according to the clipping survey. Of the 435 ads, 249 were for weight-loss products. Diet pills accounted for most of those, with 218 ads. That figure was ballooned somewhat by a number of ads for the so-called grapefruit pill ("No dieting—eat all you want; the pill does it all—$12 for a 14 day supply"). A total of 102 grapefruit pill ads were found in publications ranging from the 4,200-circulation weekly *Times* in Willard, Ohio, to the 358,265-circulation *Denver Post*. The ads appeared at a time when the U.S. Postal Service, acting in part on information supplied by FDA, was taking action against the pill's promoters, Citrus Industries. The Postal Service sought court permission to send all of Citrus Industries' mail back to the senders, thus cutting off those $12 checks. A federal court in Los Angeles ordered the mail held until a Postal Service judicial officer decides on the value of the product. In the meantime, Citrus Industries has quit advertising the grapefruit pill.

Hair restoration schemes are next in popularity to diet hoaxes, the clippings indicate. Eighty-nine ads for hair restorers were found, 42 of them for products and 47 for "clinics." FDA has counseled consumers that no product has ever been approved as safe and effective for preventing baldness or restoring hair. Wrinkle removers were also high on the quack ad hit parade.

The clippings indicate that California, our most populous state, is the best place for a quack to advertise his bogus goods and services. Eighty-four of the ads were from publications in that state. Texas was second with 45 clippings; New York contributed 44.

There was no end to the imaginations of the promoters. One product was guaranteed to take care of hemorrhoids, varicose veins and indigestion. One of the many hypnosis plans promised to handle the urge to smoke, hypertension and overeating. Although experts say exercise is necessary for most people who want to lose weight, dozens of hucksters are promoting diet products that let you "lose while you snooze."

There were "rear end kits" for reshaping, pills for the "ultimate orgasm," and a $19.95 product that would "add 2 to 4 inches to your height in just 10 weeks." But all is not harmless fun and games in the health fraud business. Tragedy is written between the lines of much of the copy. Offers of cheap, quick ways to treat heart disease, arthritis, alcoholism, depression and high blood pressure are bound to be taken seriously by someone. And that someone is most apt to suffer even more as a result. ■

Roger W. Miller is director of FDA's communications staff.

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Quackery and the ELDERLY

Quackery
and the Elderly

Quackery, the ages-old practice of health fraud, has progressed from innocuous-oil cure-alls to a high-tech multibillion dollar business. And today, much of the modern day snake-oil salesman's pitch is targeted at the nation's growing population of elderly, who suffer the diseases quacks like most to claim they can "cure."

A congressional committee has estimated that Americans spend as much as $10 billion a year on fraudulent medical therapies, and that 60 percent of quackery victims are older citizens. Often, they're hit twice as hard by health fraud, because many seniors already are shouldering big expenses for health care.

It's not that America's elderly are more gullible; quacks aim their health hoaxes at every population group, regardless of age, sex or color. And, because they don't have to hold credentials or degrees or prove their scientific expertise, these purveyors of magical panaceas can claim to cure virtually any medical problem.

But the quack's specialties are the chronic incurable diseases for which modern medicine has yet found no cure. Many are diseases that accompany old age, such as cancer, arthritis and diabetes. As a result, the elderly are prime territory for health fraud and particularly susceptible to the fraudulent promises of nonsense medicine.

Consider these statistics about Americans over 65 years of age and you'll see why they may be most vulnerable to quackery:

- More than one-third—35 percent—assess their health as only fair or poor, according to a survey by the American Association of Retired Persons.
- Most all older Americans have at least one chronic condition. Half have arthritis, 39 percent have high blood pressure, 30 percent

have hearing problems, 25 percent suffer heart conditions, 17 percent orthopedic problems, 15 percent have cataracts or sinus ailments, 10 percent have vision difficulties, and nine percent have diabetes. And many seniors have more than one of these problems.

- Normal activities are restricted one day of every 12 because of illness or injury.
- While older Americans represent less than 12 percent of the population, they take 25 percent of all prescription medicines, and their care will account for one-third of the nation's total annual health care bill.

In addition, some experts believe that because older Americans are less mobile, they're more likely to shop by mail, a favored delivery system of quacks. Medical con men hawk their wares in magazines, newspapers and even on television and radio, making their products readily available by mail or by calling an 800 toll free number.

Is it any wonder, then, that quacks tailor much of their nonsense medicine to the elderly?

Modern medicine offers a plethora of remarkable new treatments which, even a few years ago, would have seemed impossible. Every day, people are given new life; hearts are transplanted, severed limbs are reattached, artificial joints take over for failing ones. High-tech medicine has become a reality.

In this environment, quackery flourishes. Modern-day medical con men are keeping up with the times, selling phony electronic gadgets and citing scientific "breakthroughs" as the basis for their cure-all medicines. They use scientific terms to talk about their products, give themselves fancy titles and claim to be affiliated with impressively named foundations. Advertisements often contain testimonials from allegedly satisfied customers.

Quacks also like to claim that their miracle cure is being held back by national health care experts and organizations such as the American Medical Association or the Food and Drug Administration. That may sound odd, but to some older Americans desperately searching for a magical medical cure, the reasoning appeals.

Regardless of the ploy, however, quackery likely fits into three main categories:

- false claims about drugs or cosmetics;
- unsubstantiated food fads and diets or unjustified food supplements; and,
- ineffective medical devices.

Miracle drugs that cannot and will never work promise to cure baldness, wrinkles, digestive problems and even cancer. Quacks claim their potions can "melt away" fat, restore youth and enhance sexual performance.

Food fads, often promoted by self-proclaimed nutrition experts, may recommend consumption of high levels of various vitamins and nutrients and blame illness on modern techniques of agriculture and food processing. One famous unproven diet calls for coffee enemas as part of an anti-cancer regime. It's totally unfounded, scientists say.

And then there are the quack devices, the bracelets, mittens and special shoes that cure arthritis, the suction pants that remove fat and the machines with impressive names that claim to cure chronic diseases but actually do nothing but empty the wallet.

Among the elderly, these approaches tend to focus on certain diseases. Usually, it is the older population that suffers the most tragic of ailments; chronic diseases that cause much pain, can't be cured or will eventually prove fatal. Faced with that, many older Americans become desperate and fall prey to the salesmen of false hope.

Here are some of the diseases quacks tell the elderly they can treat or cure:

Cancer

While cancer strikes all ages, it is primarily a disease of advancing age. People over 60 years of age account for 60 percent of all cancer deaths.

Such statistics are rich fodder for quacks. Some experts say as much as $5 billion is spent each year on worthless cancer tests and treatments and some surveys show that as many as half of all cancer patients seriously consider or try some unproven cancer therapy.

For some diseases you might argue that quack remedies at least do no harm—even if they also do no good. But the argument doesn't hold for cancer. The special danger of fraudulent cancer treatments is that they will delay or completely replace needed medical care. Because delays in cancer treatment can prove fatal, quack cancer cures are all the more cruel.

Confusing the issue is recent medical evidence that diet can reduce the risk of getting cancer. The American Cancer Society has issued dietary guidelines to help Americans reduce their chances of developing certain cancers, but, while there may be a connection between diet and cancer, there is no evidence that it provides guaranteed protection against the disease or that diet can be used to treat it.

Nonetheless, the new scientific findings provide an abundant source of material for quacks, who often claim that cancer is a result of imbalances in the human body that can be cured by diet. Extreme cancer diets espoused by health frauds may call for "detoxification" through enemas and consumption of abnormal amounts of certain foods and vitamins, minerals and nutrients. Some of them even recommend avoiding "toxic" proven cancer treatments like radiation and chemotherapy.

Beware of foreign clinics that specialize in cancer cures. Some promoters often contend that they must operate in another country because U.S. authorities won't approve their product or therapy. Don't believe it. In some cases, they are operating outside the U.S. because they violate U.S. laws that protect people.

Arthritis

No disease causes distress for a greater number of people than arthritis, the nation's number one chronic crippling disease.

One of seven Americans suffers from arthritis, and nearly every individual who lives long enough will know its pain. The federal government estimates that 97 percent of Americans over 60 years of age have arthritis that is severe enough to be detected on an X-ray.

Despite its prevalence, doctors don't understand what causes arthritis; they have no cure for it and little in the way of treatment. Nonetheless—or perhaps because of it—Americans spend more than $2 billion a year on questionable arthritis remedies, says the Arthritis Foundation. That's more than is spent on arthritis research, the foundation points out.

One of the reasons arthritis quackery thrives is that the symptoms of arthritis wax and wane mysteriously, so that use of a phony treatment may coincide with a temporary remission of pain. And presto! The quack therapy is credited with the improvement.

In actuality, an endless number of chemical preparations have been tested in treatment of arthritis pain. A few have shown to provide temporary relief or ease symptoms; none cures the disease.

Every possible form of quackery is used to bait arthritis sufferers. There are alleged dietary cures, drugs and serums, hormone therapies, herbal medicines, snake venom treatments and even bee sting therapy. In fact, only the form of arthritis known as gout responds to changes in diet.

Then there are the miracle devices, like the radiation slippers and mittens supposedly filled with radioactive uranium ore. One of the great arthritis hoaxes of all time is the notion that sitting in a uranium mine will cure the disease. So, too, have copper and magnetic bracelets been claimed to help. Light therapy, massages, blood transfusions, laser therapy and moon dust wring money from a population desperate for relief from pain.

And, they apparently succeed—in making more trips to the bank. Some surveys suggest that as many as 90 percent of arthritis sufferers try at least one quack remedy.

Anti-Aging Treatments and Cure-Alls

Perhaps the fastest growing field of quackery lies in so-called "youth cures," or anti-aging efforts. While many of these fountains of youth appeal to younger and middle-aged Americans, they also find an audience among the older, who may hope to reclaim some of their lost energy and youthful appearance.

There are creams that claim to make wrinkles and crows feet disappear, pills that promise to restore the pep and vigor of youth, or revitalize the memory, and special tonics that hold out the hope of restoring lost hair. While such products appear harmless and seem mostly to promise a return to days gone by, there are some that could prove dangerous.

Mail-order treatments for prostate problems are one example. A man who opts for this advice and neglects honest medical care may make his ailment worse. Energy pills may contain large doses of "miracle" ingredients that can lead to medical and health problems.

Particularly alarming is the recent wave of anti-aging diet books that employ a range of gimmickry. There are those that advise near starvation diets, those that recommend fasting and those that emphasize taking a wide range of vitamins and minerals to promote longevity. Such dietary fads have no scientific basis and, in fact, may be harmful to health.

What People Can Do

While local and federal agencies work hard to control quackery in the United States, older Americans themselves can do much to prevent themselves from falling prey to medical fraud. Most important is that they always question promotions that claim that a product will produce miracles. Miracles aren't for sale through the mail or over the phone.

They should learn to recognize the language of quackery. That's not difficult because quacks tend to speak a special language of medical fraud. And they should be wary any time they read of, or hear of:

- Any treatment or product offering or guaranteeing a "cure." In legitimate medicine, cures are actually few and far between.
- Promises of complete relief from pain.
- Products and treatments advertised with the use of key words such as "breakthrough," "exclusive," "secret," "miracle," and "special." These words are not used by doctors or legitimate health care practitioners.
- Health remedies sold door-to-door by peddlers or self-proclaimed health advisors who travel from town-to-town selling their

products at public lectures. High pressure sales tactics and one-time-only deals are clues that something is wrong.

- Testimonials from satisfied users. Rarely can they be confirmed. Frequently no last names are used, or only initials. Sometimes, the testimonials are made up.
- Products that claim use of so-called "natural ingredients." The definition of "natural" is a tough one, and the word is frequently overused.
- Any therapy or product that claims to treat a large number of illnesses.
- Claims that a treatment is being suppressed by the existing medical establishment or that it is approved by the U.S. Food and Drug Administration. Federal law does not permit the mention of "FDA" or the U.S. Food and Drug Administration in any way that suggests marketing approval for any drug or medical device.

Once the language of quackery is recognized, people can protect themselves. The elderly, like other people, should be reminded that before they buy any medical product—be it dietary advice, medicine or some device—they should find out everything they can about it.

For checking out a product, the local Better Business Bureau can often provide information about the seller of the product and if he operates a legitimate business. The local medical society, usually a chapter of the American Medical Association, should be able to help as well. And, by all means, any treatment a person is considering should be discussed with his or her doctor—before it is tried.

Just because a product is backed by researchers or institutions with official and impressive names doesn't mean it is effective. Many of these titles may be fictitious. Potential buyers should tell the seller they want time to check it out. If it's a legitimate treatment, it will still be available after it is checked out.

People who believe they've been taken advantage of by medical fraud should immediately contact their local medical society, local health department, Better Business Bureau or other agencies. A person may not be able to get his or her money back, but the contact may prevent the medical con men from selling more fraudulent cures. The product label or advertisement will help officials track down the con men.

But most important, whatever is done, legitimate medical care should not be delayed in order to try an alternative treatment. The time lost could prove fatal.

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Food and Drug Administration
HFE-88
5600 Fishers Lane
Rockville, Md. 20857

THE BIG QUACK ATTACK:

MEDICAL DEVICES

January 1980

U.S. Department of Health and Human Services

Public Health Service

Food and Drug Administration

The Big Quack Attack: Medical Devices

Read Any Good Ads About Fake Medical Devices Lately?

How about the copper bracelets that cure your aches and pains? Or a pyramid over your bed that gives you energy?

And those wonderful machines that not only diagnose all manner of diseases—but also cure them with the flick of a switch or the turn of a knob?

Do you know about the vibrating belts that bounce your bulges away?

And do you know that the earth is flat? Imagine that!

Sure it's easy to laugh at these "miracle" cures and super body builders you find advertised in many of America's most popular newspapers and magazines. But there's also a darker side to this modern "medicine show"—most of these health ads are false or misleading.

Quack products and quack promoters are trying to make a million and not caring a hoot about the lies they tell and the danger of the products they sell.

These quacks say they sell medical products. But they actually sell something else, something that all of us need at some time in our lives: HOPE. Not gadgets...not diets...not cures. Just hope to people who need it badly. And that's no laughing matter.

According to some estimates, we Americans spend millions of dollars each year on medical device frauds to fulfill our hopes. Hope to look younger. Hope to cure arthritis. Hope to lose weight. Hope to love better. Hope to live longer.

Some of these quacks play to our vanity—a persons' hope for a larger bust or fewer wrinkles. Buying and trying their phony products may cost $9.98 plus postage but no real harm has been done.

Other promoters of fake medical devices peddle false hope to the sick or dying, and laugh all the way to the bank. They sell the kind of hope that can turn a patient away from proper medical treatment that may diagnose early stages of cancer or relieve the pain of arthritis.

These quacks tempt people with useless products that waste precious time—and may even be harmful.

How do these quack health promoters get away with their lies and fake products? Why can't we spot, check, and publicize the quacks? It isn't easy. Despite strict laws against false advertising and misbranding of consumer products, the market for health rip-offs is still big—and dangerous—business. And, to be perfectly honest, they're a lot smarter and a lot quicker than we like to think.

Truth in Advertising

A recent national poll indicated that more than 50 million adult Americans agreed with this statement: "Advertisements about medications and health aids must be true or they wouldn't be allowed to print them."

That would be grand if it were true...which it isn't. But, given all the laws protecting us—Federal Food, Drug and Cosmetic Act; Truth in Advertising Act; Mail Fraud and False Representation Statutes—and the major government agencies that enforce them—Food and Drug Administration, Federal Trade Commission, U.S. Postal Service—how do these swindlers and their ads get by?

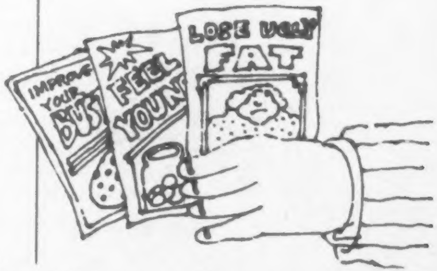
The Media View

The media—newspapers, magazines, radio and TV—have several functions: to inform, to entertain, to make money for stockholders, and to carry advertisements. But most of the media do not screen ads for truth or accuracy.

Except for certain medical and health publications, very few include doctors or qualified health experts on their staff.

It has been noted that the hardest-hitting anti-quackery articles always appear in publications that don't make money from the quacks.

Take a look through any of these current popular magazines and newspapers and you will find ads with false or misleading claims about some fake medical device or treatment: Cosmopolitan, Glamour, Modern Romance, Parade, The National Enquirer, and many others.

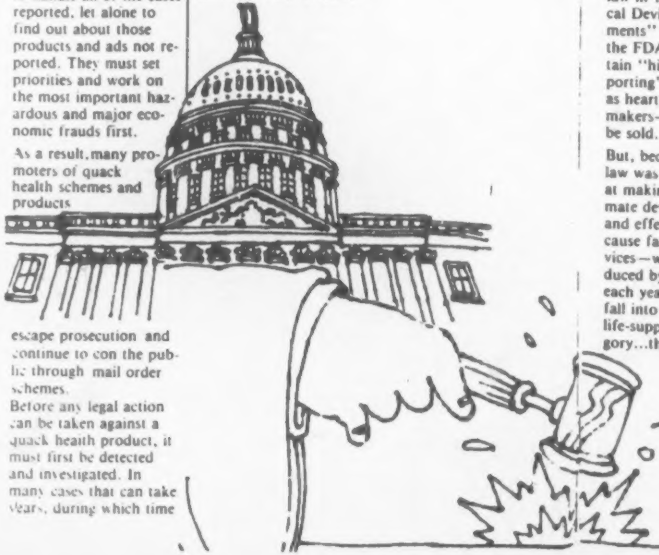


The Government View

And what about the government…those Federal agencies that are actively involved in consumer protection activities by law?

The truth is that as active and conscientious as the government is in locating, pursuing, and cracking down on health swindles, most agencies don't always have the staff or resources needed to handle all of the cases reported, let alone to find out about those products and ads not reported. They must set priorities and work on the most important hazardous and major economic frauds first.

As a result, many promoters of quack health schemes and products escape prosecution and continue to con the public through mail order schemes.



Before any legal action can be taken against a quack health product, it must first be detected and investigated. In many cases that can take years, during which time the promoters are still raking in millions on products of false hope.

Other delays can also keep these rip-offs on the market. The U.S. Postal Service has problems with "fly-by-night" quack promoters, who, after being prosecuted once, simply change their names or the name of their product and start all over again.

And the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) are often stymied by promoters who appeal their convictions again and again, while their fake products stay on the market.

In 1938 Congress passed a law called the "Federal Food, Drug and Cosmetic Act." The Food and Drug Administration was charged with protecting the public from worthless foods, drugs, and medical devices.

Congress passed a new law in 1976, "The Medical Device Amendments" which requires the FDA to approve certain "high-risk, life-supporting" devices —such as heart pacemakers—before they can be sold.

But, because this new law was aimed primarily at making sure legitimate devices are safe and effective, and because fake medical devices—which are produced by the thousands each year—don't always fall into this "high-risk, life-supporting" category…the FDA has only two ways to launch a major BIG QUACK ATTACK.

First, by proving through the courts—which is time-consuming and expensive—that these devices are indeed fakes and frauds, and second, by helping you—the consumer—to protect yourself. In reality, then, it's much easier for a swindler or quack to get his product on the market than it is for the government and others to take it off the market.

So when it comes down to the facts of life about the ads you read for many health products the rule of thumb is this: "If it sounds too good to be true, it probably is."

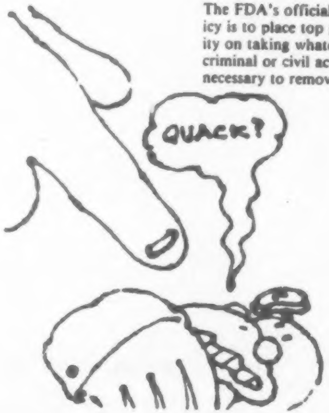
Pick a Quack...
Any Quack

Health rip-offs, or quackery take in a lot of territory. By "quackery" we don't just mean people but also their products. Says the Food and Drug Administration: "Quackery is misinformation about health."

The FDA lists three major types of hazards associated with medical device quackery:

DIRECT HEALTH HAZARDS. Buy these products and they can harm your health when you use them as directed in the labeling or advertisement.

The FDA's official policy is to place top priority on taking whatever criminal or civil action is necessary to remove these products from the marketplace.



INDIRECT HEALTH HAZARDS. If you use these ineffective products, they can indirectly harm your health because their use delays or replaces proper medical care at a time when you really need it.

The FDA's official policy regarding Indirect Health Hazards is to take legal action under its authority if the device:

1) Is promoted or distributed on a nationwide basis (through advertisements in nationally distributed magazines, for example), and 2) Is advertised or labeled for the treatment of a serious illness (such as arthritis or heart disease).

ECONOMIC FRAUDS. These products pose little or no health risk, but they will cheat you out of dollars spent on useless products that claim wondrous—but phony—effects.

The FDA's official policy regarding economic frauds is to take legal actions under its authority against these devices, if the device: 1) Is promoted or distributed on a nationwide basis, 2) Is labeled with minor health claims that are

unsupported (not proven scientifically), and 3) serves no legitimate purpose.

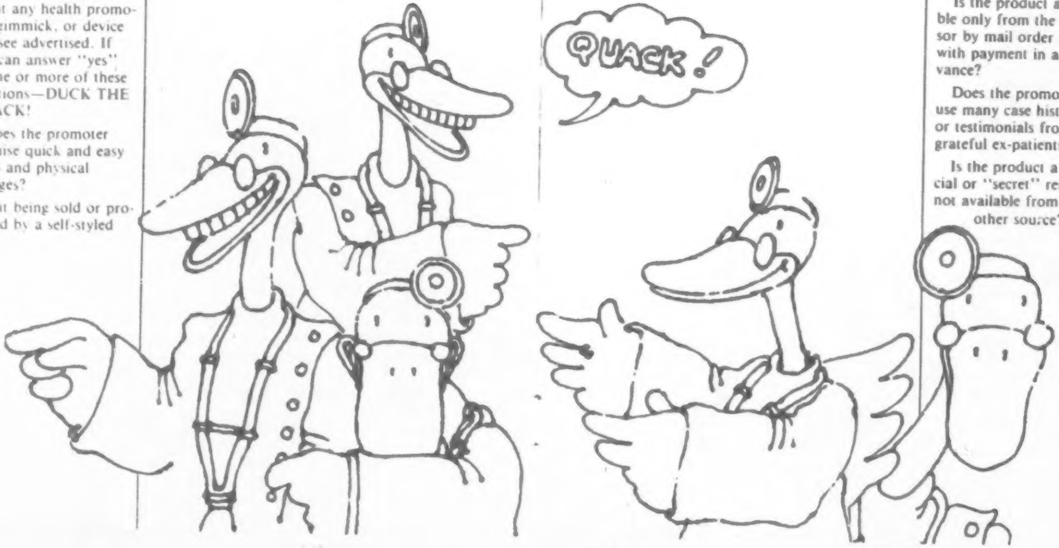
For these types of fake devices, the best way to protect yourself is by being a well-informed consumer.

Find out about these products before you buy or use them. Not only will you keep your hard-earned money—you'll also protect your health.

Health quackery has some tell-tale characteristics. Here are a few questions to ask yourself about any health promoter, gimmick, or device you see advertised. If you can answer "yes" to one or more of these questions—DUCK THE QUACK!

Does the promoter promise quick and easy cures and physical changes?

Is it being sold or promoted by a self-styled health advisor, a crusading organization, a faith healing group, or in popular magazines?



Is it advertised as being good for a wide variety of ailments?

Is the product advertised to treat a condition that medical science has not found a treatment for?

Does the sponsor claim persecution by the medical community and the government because they do not accept this wonderful discovery?

Is the product available only from the sponsor by mail order and with payment in advance?

Does the promoter use many case histories or testimonials from grateful ex-patients?

Is the product a special or "secret" remedy not available from any other source?

The Nine Faces of Quackery

The FDA has grouped quack medical devices into nine general categories—ranging from figure-enhancing devices like bust developers to mysterious cure-all devices like pyramids.

On the last pages of this booklet you will find a handy reference chart showing each of these nine types of device quackery along with a list of devices—by brand name— that the FDA or the U.S. Postal Service have found to be fakes and phonies, plus any legal actions that have been taken against the manufacturer or distributor of these products.

What are some examples of the FDA's nine categories of modern quack medical devices on the market today and what do they claim to do?

Fact versus Quack.

1. Figure Enhancers
Quack: ". . . Develop or increase the bust size in days; for shaping thighs, spot reducing; lose inches while you sleep; melt down fat."

Fact: No exercise device can increase the size of the bust . . . only the chest muscles under and to the side of the breast. Nothing can cause weight loss except controlling what and how much you eat and exercising regularly.

2. Arthritis & Pain Relievers
Quack: ". . . Relieves or cures arthritis or other pain."

Fact: At this time there is no known "cure" for arthritis or relief for all types of pain.

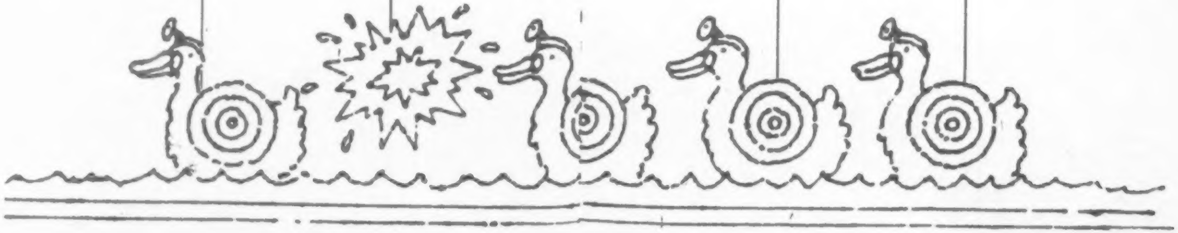
3. Sleep Aids
Quack: "Neutralizes anxiety by producing electrical impulses which cause natural sleep."

Fact: Because sleeplessness has many causes, there is no one cure for it.

4. Hair and Scalp Devices
Quack: ". . . Increase hair growth, eliminate baldness with synthetic hair implants, or remove unwanted hair painlessly and permanently."

Fact: No device can cure baldness or make hair grow. Hair is not like a plant; once it is gone it cannot grow back. And generally, over-the-counter (non-prescription) do-it-yourself electric hair removal devices may damage the skin, can be painful, and hair removal may not be permanent.

The implanting of polyester or modacrylic fibers into the scalp has been shown to cause serious infections, bleeding, and loss of natural hair; avoid this artificial (synthetic) hair implant procedure and any clinic that promotes it.



5. Youth Prolongers
Quack: ". . . Eliminates wrinkles and restores youthful facial contours, stops skin aging."

Fact: No device or treatment can remove or prevent wrinkles or change facial shape—except plastic surgery performed by a skilled physician. No device can cure or prevent the aging process.

6. Sex Aids
Quack: ". . . Effective for impotence regain vigor; for frigidity."

Fact: No known device or single treatment can cure impotence or frigidity. These are symptoms of more serious disease or psychological problems that only a doctor can diagnose and treat. Some of these devices can actually cause pain and injury.

7. Respiratory, Pure Air & Water Devices
Quack: ". . . For destruction of bacteria and TB germs, reduce aging process, treat anemia and muscle pains."

Fact: Air purifiers or "Negative Ion Generators" have not been proven to be of value in preventing diseases or improving health. Water filters, however, can make your water taste better by removing some dirt or chemical taste and odor.

8. Disease Diagnosers
Quack: ". . . For diagnosing numerous diseases, chronic and crisis patterns, nerve pressure analysis, and "do-it-yourself" detection of early cervical cancer."

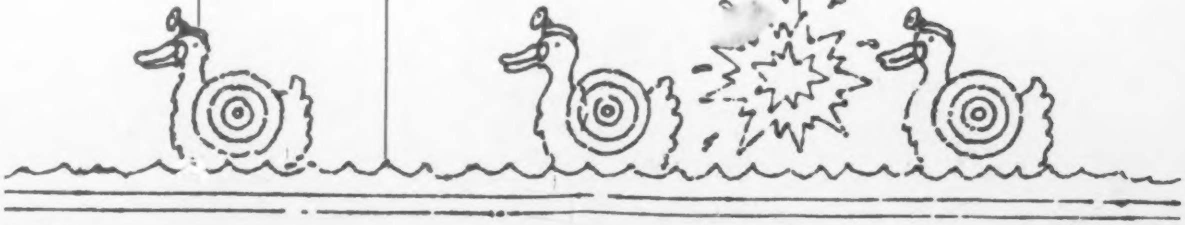
Fact: There is no one device capable of diagnosing all or a wide variety of diseases. Beware of a practitioner who says he can diagnose and treat any disease you have merely by turning dials on a machine and placing electrical contacts on your body. These devices and so-called "doctors" are quacks.

Remember, too, that believing ads that promote medical devices for "do-it-yourself" diagnosis or "self-treatment" of diseases and illness can also be dangerous. A wrong diagnosis. . . wrong results . . . or a fake treatment that really does nothing, can delay proper medical diagnosis and treatment by your doctor. And, by then. . . it may be too late for any treatment.

If you experience unusual physical symptoms that tempt you to diagnose and treat your condition yourself—Don't. Do-it-yourselfers are the easiest prey for the quacks.

9. Cure-Alls
Quack: ". . . For fatigue, asthma, stroke, polio; effective against cancer, leukemia; increases fertility; halts illnesses caused by pollution."

Fact: No device exists that can treat or cure a variety of illnesses from corns to cancer! The quacks who sell these devices are professional "con men" who want you to gamble on their fake products. . . and lose. You can almost bet your life on it.



Where to Report Quack Device Problems

(and get more information)

People get embarrassed when they find they've been "had." They tend to keep quiet about it. Silence is a quack's best friend. If nobody speaks up, dangerous or worthless products could be on the market forever. Publicizing a quack is just about the most public-spirited thing you can do.

If you think you've run into a quack or a quack product, be sure to protect yourself first. Nobody's quack-proof. But an alert, well-informed consumer can usually beat the con artists at their own game.

If you'd like to know more about protecting yourself against health quackery, look here:

- If the device has made you ill, contact your family doctor.
- If you haven't used the product yet, consult your family doctor and call the local offices of the Better Business Bureau, State Consumer Protection Agency or State Attorney General, U.S. Postal Service, or the Food and Drug Administration. They'll be able to tell you if they've had complaints about the product or the promoter.
- For information on medical devices used for specific diseases, contact organizations in that medical field (American Cancer Society, National or State Associations of the Deaf, Arthritis Foundation, etc.).

But...Don't Stop There

Report your problem to the proper government agency, too. Here's who to report the problem to, and how to report it:

- *About products made and sold within one state only:* Local or state health department, attorney general, or consumer protection agency.
- *About suspected false advertising: (either in a publication or on radio or TV):*

FEDERAL TRADE COMMISSION (FTC)

6th Street and Pa. Ave., NW, Washington, DC 20580 (or check with your regional FTC office)

- *About quack products bought by mail:*

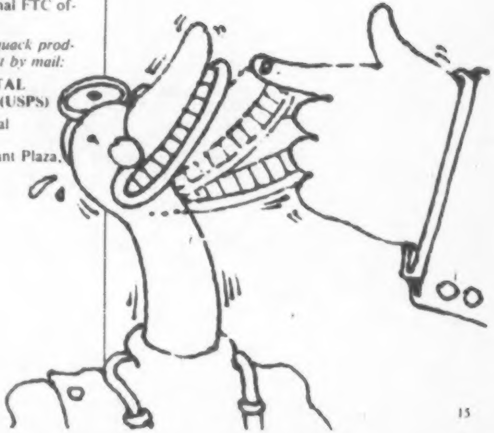
U.S. POSTAL SERVICE (USPS)

Chief Postal Inspector,
475 L'Enfant Plaza,
Washington, DC 20260
(or check with your local postmaster)

- *About a medical device that is mislabeled, misrepresented, or is otherwise harmful:*

FOOD AND DRUG ADMINISTRATION (FDA)

Call your local FDA office listed in the telephone directory under U.S. Department of Health, Education, and Welfare or its new name: U.S. Department of Health and Human Services, or contact Bureau of Medical Devices, HFK-125, 8757 Georgia Ave., Silver Spring, MD 20910



How to Report Quack Device Problems

- Report the problem as soon as possible, giving your name, address, and telephone number.
- Explain the problem you've had with the product.
- Give the name and address of the store or mail order firm where you bought the article, and the date of purchase. If you bought a health service or treatment, just tell from whom you bought it and where the company is located.
- Describe the product and its label (photo copy it if possible) and give any code marks that appear on the container.
- Save whatever is left of the product to show to your doctor or the FDA, if they ask.

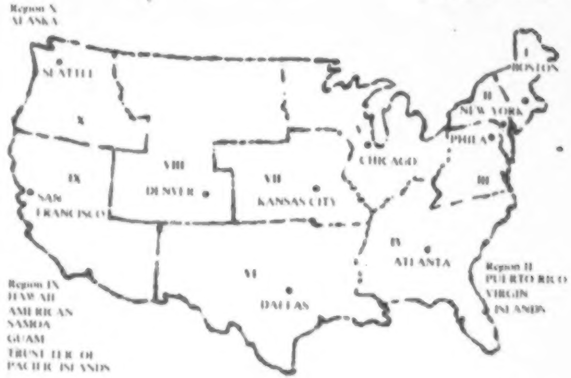
Remember: The few minutes you take to report a possible health fraud or hazard may keep you, your family, and others from being cheated out of health and money. You could even save a life!

Need More Information?

If you would like more information about medical devices and FDA regulations, write to: **Food and Drug Administration, Bureau of Medical Devices**, Consumer & Regulatory Affairs Branch (HFK-131), 8757 Georgia Avenue, Silver Spring, MD 20910.

Some of the information contained in this booklet was previously published in the May 1978 issue of CURRENT CONSUMER, and incorporated here through the courtesy of its publisher Curriculum Innovations, Inc., Highwood, IL 60040

FDA District Offices



Albany, NY	(518) 427-6043
Atlanta, GA	(404) 881-3162 (404) 881-7355
Baltimore, MD	(301) 962-4012
Boston, MA	(617) 223-5067
Brooklyn, NY	(212) 965-5301 (212) 965-5043
Buffalo, NY	(716) 846-4478
Chicago, IL	(312) 353-7379 (312) 353-7126
Cincinnati, OH	(513) 684-3504
Cleveland, OH	(216) 522-4802
Dallas, TX	(214) 749-2735
Denver, CO	(303) 837-4915
Detroit, MI	(313) 226-6260
East Orange, NJ	(201) 645-3023 (201) 645-6365
Falls Church, VA	(703) 557-0389
Grand Rapids, MI	(616) 456-2340
Indianapolis, IN	(317) 269-6500
Kansas City, MO	(816) 374-5850
Los Angeles, CA	(213) 688-3776
Minneapolis, MN	(612) 725-2121
Nashville, TN	(615) 251-5851
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Omaha, NE	(402) 221-4676
Orlando, FL	(305) 855-0900
Philadelphia, PA	(215) 597-4390
Pittsburgh, PA	(412) 644-3394
Richmond, VA	(804) 782-2564
Rockville, MD	(301) 443-4166
San Antonio, TX	(512) 299-6735
San Francisco, CA	(415) 556-0318
San Juan, PR	(809) 753-4443
Seattle, WA	(206) 442-5304
St. Louis, MO	(314) 425-4137
Call Toll-Free Anytime	(800) 638-6725

FDA Consumers Guide to Quack Medical Devices.

Figure Enhancers

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
THERMOSLIM P-Ryton Corp. Long Island City, NY	Electric Heating Pad for Reducing Weight	For reducing...Helping destroy thick fat deposits... Benefiting muscles like 2 hours of exercise...
DERMAPHORESIS P-Ryton Corp. Long Island City, NY	Electric Massager for Reproportioning and Contouring the Body	For reproportioning... Helping to destroy thick fat deposits...
VIBROELECTRONIC P-Ryton Corp. Long Island City, NY	Electric Muscle Stimulator for Circulation (Vasodilator) to Reduce Weight	For stimulating and improving circulation... Benefiting muscles like 2 hours of exercise...
SEAN MICHAEL'S BUST EXPANDER Sean Michael's St. Petersburg, FL	Isotonic Exerciser (Bust Developer)	Increase the size of the breast ...Increase bustline measurements 3½ inches in 14 days, 5½ inches in 21 days... Cause the breasts to become rounder, higher and firmer... New invention using "pectoral isolation" principle... Results achieved by use 3 minutes a day...

Arthritis And Pain Relievers

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
ALL-PURPOSE MASSAGERS All-Purpose Massager Co. Fort Worth, TX	Heating Pads and Ultra-high Frequency Motor-Driven Vibrator for Pain Relief	For relief of pain associated with spurs on the spine, dislocated discs, arthritis... Traffic accident-caused pain...Arthritis shoulder, spine and wheelchair pain ...Return semi-invalids to work in days or weeks... Can massage entire body completely at one time...
ACU-DOT Acu-Dot Corp. Akron, OH	Small Round Adhesive Bandage Patches with Tiny Magnets Attached	For temporary relief of occasional minor aches and pains of muscles and joints...
REFLEXORCUSHIONS Nutritional Life New York, NY	Reflexology Massage Therapy using rubber shoe inserts with ventilation ducts for "air flow"	Instant relief from tired, aching feet...Massaging action with every step... Chinese claim this action benefits the body's entire nervous system...
MAGNETIC AND COPPER BRACELETS, CROSSES, BELTS, AND OTHER SIMILAR JEWELRY. (Various manufacturers and distributors, primarily through mail order.)	Common jewelry made of copper or other metals with magnetic properties	For relief of aches and pains in joints...Tennis elbow...Backache...Miracle arthritis "cure"...Copper is considered to have "miraculous curative powers" for arthritis and other pain...Magnetism is said to "draw out pair" from the body *mysteriously*...

Sleep Aids

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
ELECTROSEDATION ELECTRONIC THERAPY DEVICE Tri-Tronics Laboratory, Inc. Euless, TX	Electrosedation: Sleep Inducement by Electric Current to Treat Insomnia	For relaxation and restful sleep...Treatment for insomnia ...

Hair and Scalp Devices

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
ROTASAGE SCALP MASSAGER Doctor's Laboratories Dr. Shiffer Laboratories Doctor's Rotasage Punta Gorda, FL	Hand-Operated, Hard-Rubber Device with Points on the Surface to Massage the Scalp to Promote Hair Growth	Increases hair growth by massage to improve circulation...Regardless of the cause of hair loss...
BIO-2000/DEPILLEX Bio-2000, Inc. Irving, TX Bea Cranford, Inc. Dallas, TX	Electronic Hair Removal Tweezer (Epilatory Device)	Safe and effective for removing unwanted hair...In seconds...Painlessly, permanently...

Disease Diagnosers

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
URINOMETER Brothers Scientific Products, Inc. Chicago, IL	Diagnostic Device to Test Urine Sugar for Diabetes ●BEWARE: THIS PRODUCT IS DANGEROUS TO YOUR HEALTH WHEN USED AS DIRECTED AS SELF-DIAGNOSING TEST FOR DIABETES	For testing sugar levels in the urine as a means of diagnosing diabetes...

Cure-Alls

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
ACU-AID ION SPHERES Tama Enterprises, Inc. Tokyo, Japan	Adhesive Patches with Small Steel Balls for Pain Relief (A type of Acupressure)	For pain ailments, specific ailments...Stiff shoulders due to tonsilitis, coughing, stiff chest...Slight cold, headache, dizziness, insomnia, toothache, low back pain, allergies...Immediate relief from muscular pain...Inflammation of joints and tendons...
FAMILON-S Hakuju Institute for Health Science Co., Ltd. Tokyo, Japan IonLab, Inc. Van Nuys, CA	Low-frequency Electric Current Applicator for Pain Relief (Vibrator/Massager)	A massager for improving spinal chord ailments,muscular tension, insomnia, lumbago, headache, eyestrain, liver trouble, menstrual irregularities, menopause, heart trouble, fatigue due to hard work... Pain of piles...Whiplash syndrome...Diseases of the respiratory, urinary or generative organs...Constipation...
"THERAPEUTIC" PILLOWS Mid-America Sales and Marketing, Inc. Bethany, OK	Neck Support Pillow	For prevention of chin and neck wrinkles...Treatment of cardiac cases...Prickling sensations with fingers...
SOLARAMA BOARDS The World of Solarama Greenville, SC Water & Chemical Corp. Phoenix, AZ The Heritage Store Virginia Beach, VA	High-Frequency Energy Generator (Electromagnetism) for Pain Relief	For relieving pain, ruptured discs, mammary (breast) cancer...Healing surgery 30% faster...Bedsores, malignant brain tumor...Bone mending... Aging...Nerves...Relaxes tension by Thermal Electron Emission...Causes rejection of cancer virus...Supplies a vital life force that supports all living matter...For arthritis and paralysis...

Hair and Scalp Devices (Cont.)

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
SYNTHETIC HAIR IMPLANTS HUMAN HAIR IMPLANTS (Other than the patient's own hair) Numerous clinics around the country such as: Syntho-Hair United Laboratories of America HRC Scientific Corp. Hairegenics Underwood Hair Adaptation Process, Inc.	Synthetic Hair Implant Technique: Artificial (polyester or modacrylic) Strands Threaded into the Scalp with Needles or by Air Guns, and Tied to the Scalp with Knots Human Hair Implant Technique: Implanting *Another* Human's Hair into the Patient's Scalp—Same Process ●BEWARE: THESE QUACK TREATMENTS ARE DANGEROUS—THEY CAUSE SERIOUS INFECTION	A "cure" for male-pattern baldness...A safe, painless and reversible surgical implanting process that guarantees a permanent, natural-looking head of hair...
DEPILATRON Various clinics and salons across the country, including: Seligman and Latz Depilatron, Inc. Depilatron Professional Centers	High-frequency Electronic Tweezers for Hair Removal (Epilatory Device)	Totally effective, totally safe, totally painless permanent hair removal...Electric current permanently destroys the hair's regenerative cells...

Skin Care and Youth Prolongers

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
ISOMETRIC BEAUTY BAND Jay Norris Corp. Freeport, NY Mark Traynor, Inc. New York, NY	Isometric Exerciser (Stretch-Pressure Band)	Gives the user a youthful appearance by strengthening facial muscles and tissues...Firms, tones and conditions the face...Cumulative results will be achieved with repeated wearing of the band...

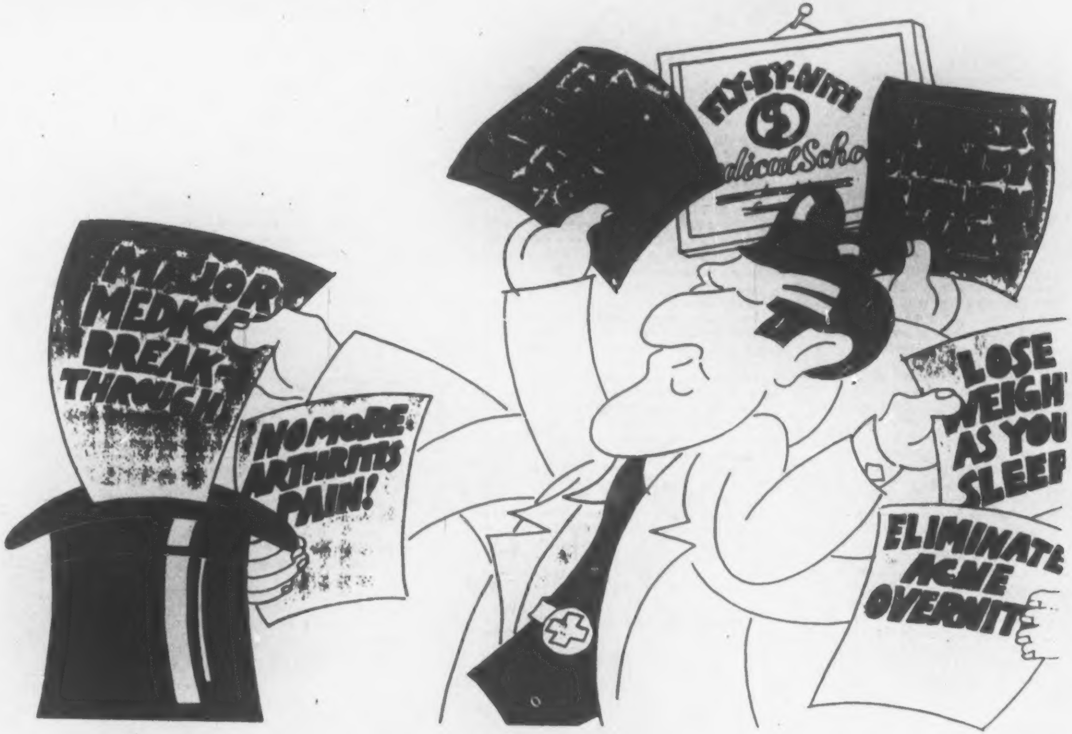
Sex Aids

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
THE COMMANDER United Medical Supply Hollywood, CA	Three Rubber Rings of Various Sizes, a Plastic Applicator Ring, and a Rubber Band. Rubber Ring is Placed on Male Organ with Applicator; Pressure of Rings Restricts Blood Supply and "Causes and Sustains" an Erection	Enables male user to achieve and maintain an erection indefinitely...For impotence...Will not harm or cause injury to user...Effective remedy for sexual problems...
CHARTHAM METHOD Modern Age Products, Inc. Hicksville, Plainview and New York, NY and Brookfield, CT	Chartham Method, together with the Vacuum Developer Device, is a Means for Increasing the Size of the Male Organ by Use of Hot Compresses, Massages, Thigh and Buttock Exercises	Enlarges dimensions of the male organ...Scientifically evaluated and proven...Result of 2 years research by a world-famous sexologist...Effective for treating impotence...

Pure Air & Respiratory Devices

Brand Name Manufacturer or Distributor	Description of Device Principle of Operation	False or Misleading Claims in Labeling or Advertising
MINI-MASK Strange Co., Inc. Belleville, IL	Disposable Nose Filter	An effective protection against head colds, hay fever, and sinus conditions...Protects against noxious dust, powder, pollens...
ENERGAIRE (Miracle Fuzz) JS&A Group, Inc. Northbrook, IL 60062	Negative Ion Generating Air Purifier (ionized oxygen)	Surrounds you with oxygen ions and cleans and purifies air...Cleans your room of odor-causing bacteria, and stale, musty, or smoky air...Not only purifies the air, but also eliminates pollen and other irritants...Allows you to sleep easier, deeper, more relaxed...

QUACKERY ...The Billion Dollar MIRACLE Busines


FLY-BY-NITE
Medical Scho
MAJOR MEDICAL BREAK-THROUGH!
NO MORE ARTHRITIS PAIN!
LOSE WEIGHT AS YOU SLEEP
ELIMINATE ACNE OVERNITE

This year, we Americans will spend billions of dollars on products that do nothing for us—or may even harm us. And we'll do it for the same reason people have done it since ancient times . . . we want to believe in miracles. We want to find simple solutions and shortcuts to better health.

It's hard to resist. All of us, at one time or another, have seen or heard about a product—a new and exotic pill, device, or potion—that can easily solve our most vexing problem. With this product, we're told, we can eat all we want and still lose weight. We can grow taller or build a bigger bustline. Or we can overcome baldness, age, arthritis, even cancer.

It sounds too good to be true—and it is. But we're tempted to try the product in spite of all we know about modern medical science—or perhaps *because* of it. After all, many treatments we take for granted today were once considered miracles. How can we tell the difference?

Separating Facts From Fantasy

Not all advertisements for health products are false, of course. In fact, the vast majority aren't. So just what is quackery? Simply put, *quackery is the promotion of a medical remedy that doesn't work or hasn't been proven to work.* In modern times, quackery is known as health fraud. But call it quackery or call it health fraud, the result is the same—unfulfilled wishes, wasted dollars, endangered health.

Often quack products are fairly easy to spot, like the magic pills you are supposed to take to stay forever young. But sometimes the products are vaguely based on some medical report that you may even have heard about in the news.

In general, when looking over ads for medicines and medical devices, watch out for those that seem to promise too much too easily. And investigate, before you participate.

The High Price of Health Fraud

Quack cures rob us of more than money. They can steal health away or even take lives. Quacks may lure the seriously and often desperately ill, such as people suffering from arthritis and cancer, into buying a bogus cure. When people try quack remedies instead of getting effective medical help, their illnesses progress, sometimes beyond the treatable stage.

Today's Targets for Quack Attacks

Quacks have always been quick to exploit current thinking. The snake-oil salesmen a few generations back carried an array of "natural" remedies to sell to a public that was still close to the frontier. And today, quacks take advantage of the back-to-nature movement, capitalizing on the notion that there ought to be simple, natural solutions to almost any problem. Some current target areas for such promotions include:

Arthritis. Over 30 million Americans suffer from arthritis, and the nature of the disease makes it fertile ground for fraud. And because symptoms may come and go, or the disease may be in remission for several years, arthritis sufferers may actually believe, at least temporarily, that they've been cured by a quack remedy.

Before you add to the $2 billion spent annually on quack arthritis cures, remember that, although medical science offers effective treatments, it has found no cure for arthritis. The list of fraudulent "miracle cures" for the disease ranges from snake venom to lemon juice, from the harmless milk of vaccinated cows to the dangerous use of steroids. More dangerous and costly arthritis treatments are offered by legitimate-looking clinics, often located outside the United States. While some clinics may offer effective treatment, many prescribe untested diets or drugs that either offer no arthritis cure or cause patients to have additional health problems. Beware of arthritis clinics that offer cures.

It is important to remember that pain relief and inflammation treatments are not the same. A product that advertises relief for the minor pains of arthritis does not necessarily treat inflammation. For this reason, the serious condition of arthritis should be treated by a doctor.

Fitness. Quacks know that people would like to have the benefits of exercise without actually exercising. So recent years have brought all sorts of "body toning" devices, such as electrical muscle stimulators. Such devices are, of course, worthless for "body toning" and can even be dangerous, but they're advertised and sold as substitutes for exercising.

Weight Loss. These schemes are probably the most popular form of quackery. Millions seek a painless way to win the battle of the bulge. Since proper diet and exercise take constant discipline and work, quack claims are especially appealing and, to some, worth a try. But quick weight-loss products aren't worth a try when they affect your health and harm you, and they can harm you if only by not helping you. Being overweight can lead to numerous health problems, including high blood pressure, heart attack, stroke, and kidney disease.

The fact is that you cannot lose weight if you do not cut down on the amount of food you eat or exercise more to burn up calories. Any product claiming that promises to trim you down and tone you up effortlessly is false. Consult your doctor before beginning any diet program, and remember, there are no medicines or devices that will let you lose weight effortlessly.

Cancer. Here quack cures are probably the cruelest and the most expensive. Seriously ill people may spend thousands of dollars on phony treatments that do nothing to relieve their disease or suffering. Often, the quack cancer treatment clinics are set up just outside the United States, so that they're beyond the jurisdiction of U.S. authorities. Before you request admission to any cancer clinic, talk to your doctor about it.

As an aid in evaluating cancer-cure claims, keep in mind that there is no one device or remedy capable of diagnosing or treating all types of cancer. Cancer cannot be detected or treated solely through the use of machines. No one medical test conducted one time can definitively diagnose cancer, nor can a machine operated by a fraudulent practitioner con-

Quack Advertising—The Need for Healthy Skepticism

Many people believe that advertising is screened by a government agency and that therefore, all claims about health products in advertising must be truthful. This is not the case with most health-care products, except for the drugs and medical devices that require pre-market approval by FDA. There is no federal, state or local government agency that approves or verifies claims in advertisements *before* they are printed. Law enforcement authorities can take action only after the advertisements have appeared.

This holds for claims of a "money-back guarantee." Many quacks are fly-by-night operators who do not respond to refund demands. Often, by the time refund requests come in, they have changed their address to avoid law enforcement officials.

Beware of Testimonials That Sound Too Fantastic to Be True

Health fraud promoters are fond of using testimonials from "satisfied users" to promote their wares. One reason they do this is that they can't get ethical health professionals to sanction their products. Legitimate testimonials may be useful sources of information about how a product works. However, beware of testimonials reporting incredibly fantastic medical results, especially when no medical support for the claim is offered. This is particularly important since "satisfied users" may, in some cases, have experienced the sugar pill, or "placebo," effect. The placebo effect occurs when people, believing they have been given a real medicine, experience a benefit from it. It is the power of suggestion at work.

You Can Protect Yourself

Apply the "it-sounds-too-good-to-be-true" test to ads for health products by watching for these common characteristics of quackery:

- A quick and painless cure.
- A "special," "secret," "ancient," or "foreign" formula, available only through the mail and only from one supplier.
- Testimonials or case histories from satisfied users as the only proof that the product works.
- A single product effective for a wide variety of ailments.
- A scientific "breakthrough" or "miracle cure" that has been held back or overlooked by the medical community.

Invest Your Time Before You Invest Your Money

Before buying a suspect product or treatment, find out more about it. Check with one or more of the following:

- your doctor, pharmacist, or other health professional
- the Better Business Bureau
- your local consumer office
- your state's Attorney General
- the Federal Trade Commission, Washington, D.C. 20580
- your nearest office of the Food and Drug Administration
- your Postmaster or the Postal Inspection Service.

This brochure is a joint publication of:
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The Pharmaceutical Advertising Council
The U.S. Food and Drug Administration
The U.S. Postal Service

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration HFI-40
HHS Publication No. 85-4200.

"BRAND X" OR "GRADE A"? -- ANATOMY OF AN AD

- contain promises about the physical results of surgery;
- contain statements about the surgical procedure;
- contain claims about the innovative character of an operation;
- contain false claims about the physician or his or her staff;
- contain so-called "before and after" photographs, with "after" photograph posed in a more favorable angle and lighting;
- show the results of one patient's experience or one person's testimonial to apparently imply and mislead other people to conclude that anyone having the same operation can and should have similar results;
- utilize truthful information in a manner that may mislead potential patients as to the qualifications of the advertising physician. An example is one physician who included his membership in the AMA as part of his qualifications. Membership in the AMA is not a function of professional skill;
- assert that a physician is qualified as a "board certified cosmetic surgeon" when no board of that title is recognized by the American Board of Medical Specialities;

- claim board certification when they are actually certified in other specialties having little or nothing to do with the cosmetic surgery procedures being performed;

- advertise credentials, perhaps impressive to lay persons but medically meaningless, including authorship of articles published in obscure medical journals;

- state doctor inventions of surgical instruments;

- state special residency training and expertise;

- claim state-of-the-art facilities and invite visits by patients who want to make comparisons. Most potential patients have no way to judge its adequacy and medical necessity, and often are mislead by the "Tokyo effect" of fancy gadgets with lights, bells and whistles to suggest safety and state-of-the-art technology;

- lure people into an office by providing something free. The staff believes such ads lead to "hard sell" techniques used once the patient arrives in the office;

- emphasize the reasonableness of fees and the easy financing that's available;

- utilize photographs of attractive models who in most cases have little or no relationship to any cosmetic surgery actually performed on the model. The staff believes that psychologically appealing advertising appears to minimize the potential health risks of these surgical procedures; and

- fail to mention even the name of the operating surgeon.

Actual
Patient Photo

"To see how I looked before Cosmetic Surgery, wrinkle this page."

Until a few years ago, facelifts that tightened the skin were the only available remedy for aging. However, many people who've had this done complain of the "pulled", unnatural look.

In the last few years, Dr. Richard Ellenbogen has developed, tested and proven a safe, natural looking, much improved alternative to the classical facelift.

This new surgical technique tightens aging muscles and sculpts unwanted fat deposits in the cheeks, neck, and the corner of the mouth that causes you to look older. This allows for a very natural appearance.

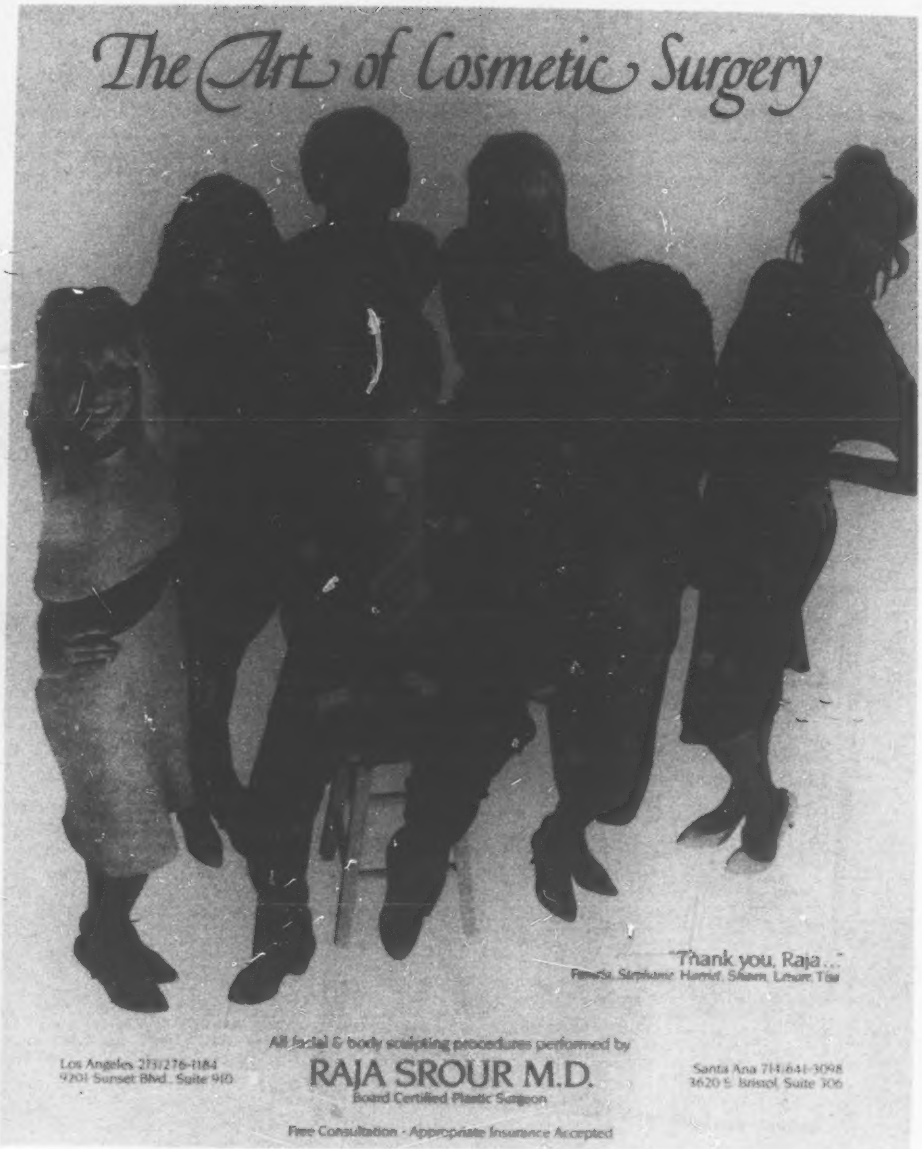
You may have seen Dr. Ellenbogen discussing this, and other face rejuvenating techniques, on *The Phil Donahue Show, Cosmopolitan, Time, Newsweek, The Wall Street Journal or USA Today.*

If you are tired of staring wishfully into the mirror and you'd like more information, give us a call.

It could change the way you look at life. And change the way people look at you.

RICHARD ELLENBOGEN, M.D.

Certified Diplomate American Board of Plastic Surgery
[illegible]201 Sunset Blvd · Suite 202 · Los Angeles, CA [illegible]
(213) 276-3183



The Art of Cosmetic Surgery

"Thank you, Raja..."
Pamela, Stephanie, Harriet, Sharon, Lenore, Tisa

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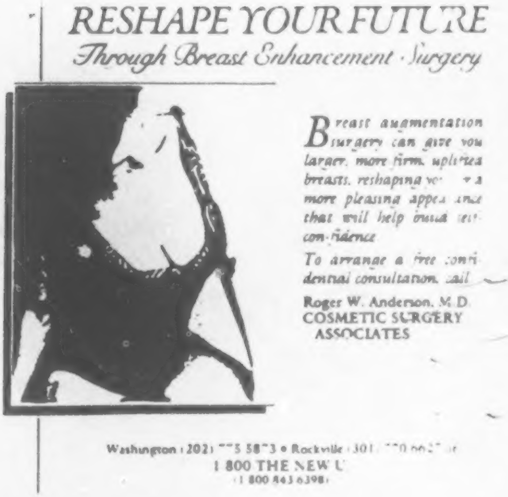

RESHAPE YOUR FUTURE
Through Breast Enhancement · Surgery

Breast augmentation surgery can give you larger, more firm, uplifted breasts, reshaping you to a more pleasing appearance that will help build self-confidence.

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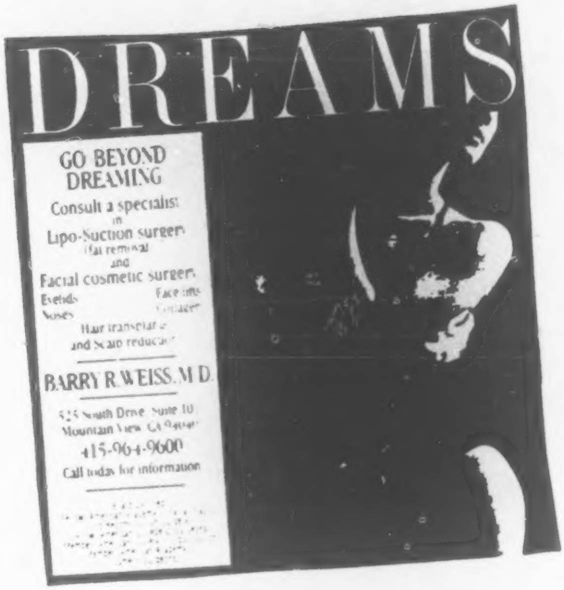

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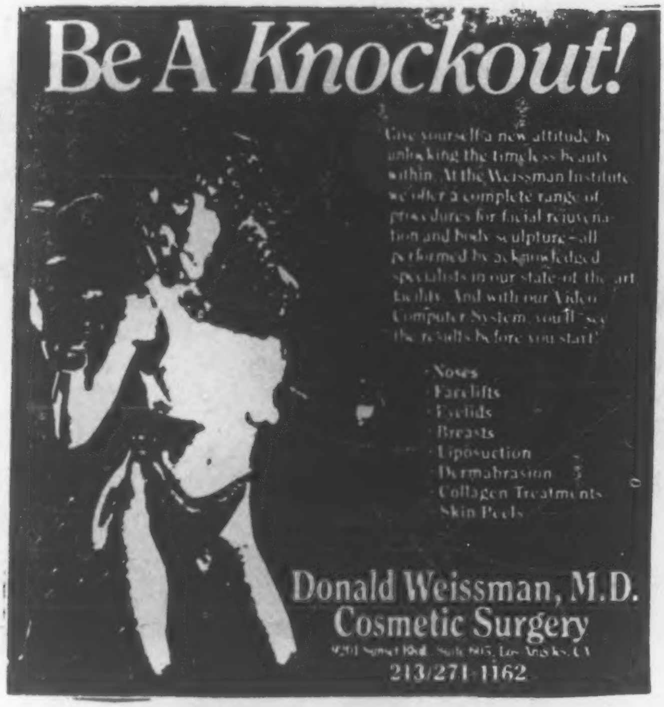

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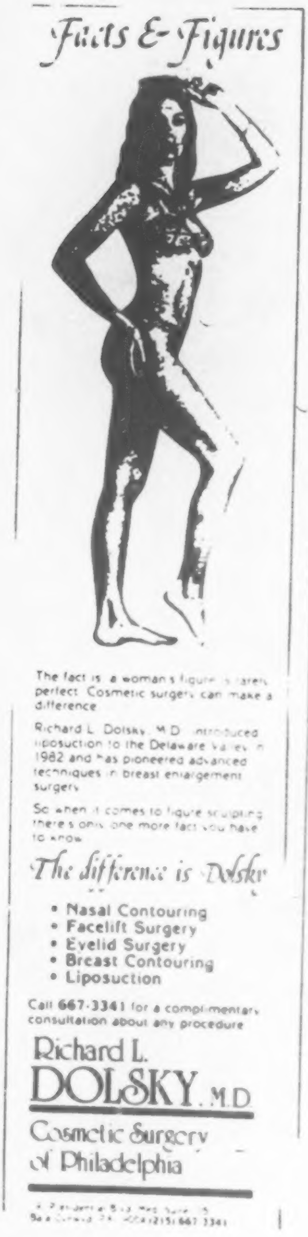

Facts & Figures

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Diets may work but are seldom long lasting. **Liposuction** [illegible] forever by surgically contouring your body [illegible] the unwanted fat from selected areas. Find out if liposuction is right for you. Call us today. [illegible] may change the shape of your future!

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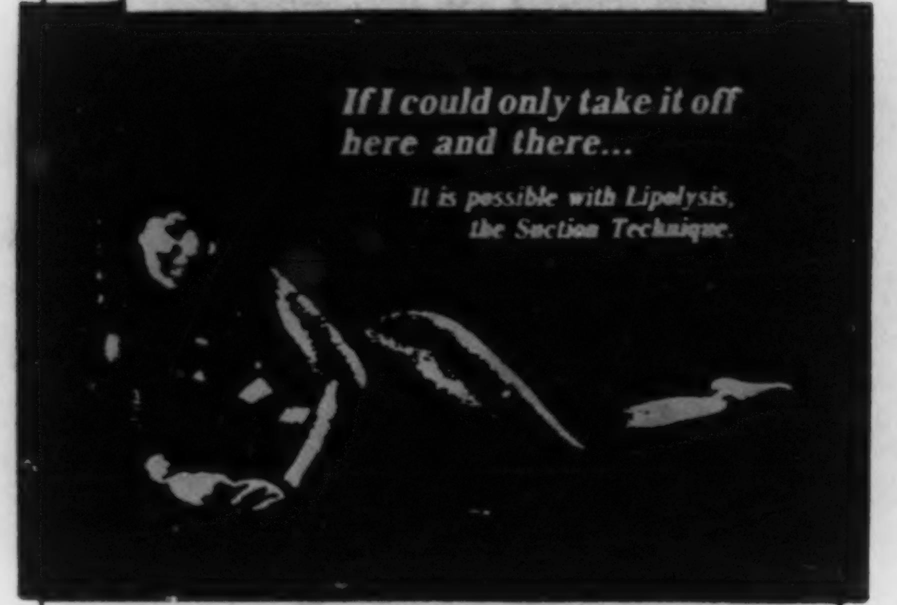
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Lipolysis is the revolutionary new procedure developed in France. It has been used since 1977.

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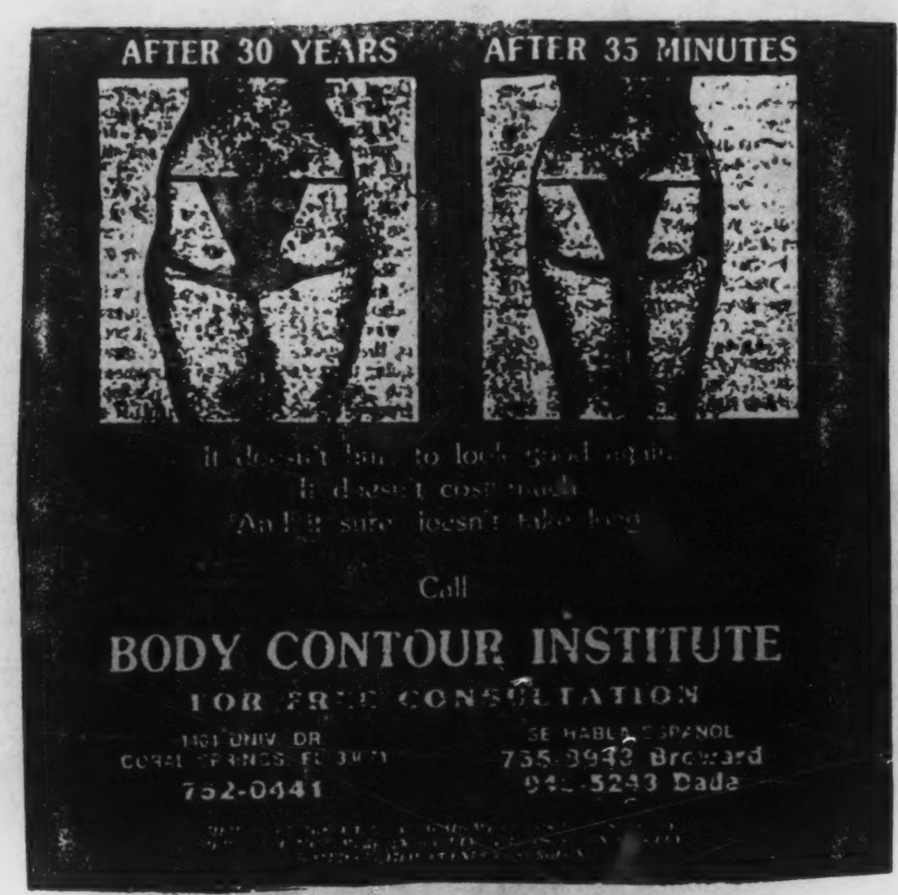

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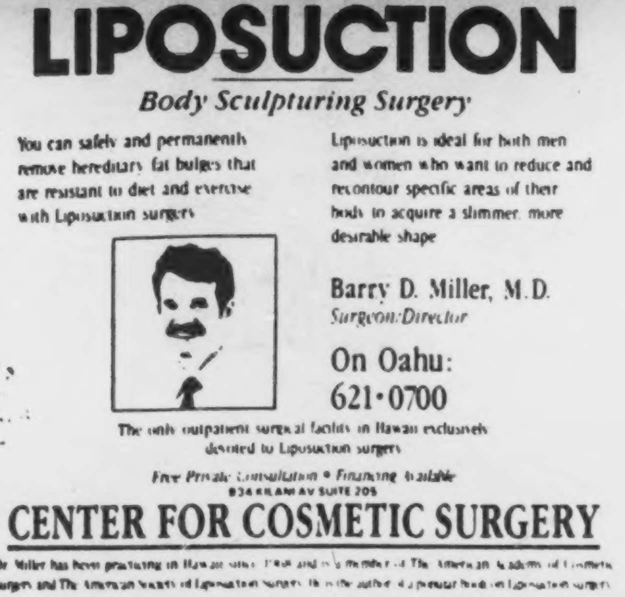

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Liposuction is ideal for both men and women who want to reduce and recontour specific areas of their body to acquire a slimmer, more desirable shape.

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Dr. Miller has been practicing in Hawaii since [illegible] and is a member of The American Academy of Cosmetic Surgery and The American Society of Liposuction Surgery. He is the author of a popular book on Liposuction surgery.

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During the consultation we will review with you the patient brochure for injectable collagen.

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Liposuction is a short procedure that can remove fat cells forever to recontour your abdomen, hips, thighs, knees and ankles to more pleasing proportions. Call for a free consultation to learn how Liposuction can change your figure and the way you feel about yourself.

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86 *The Washingtonian/April 1988*

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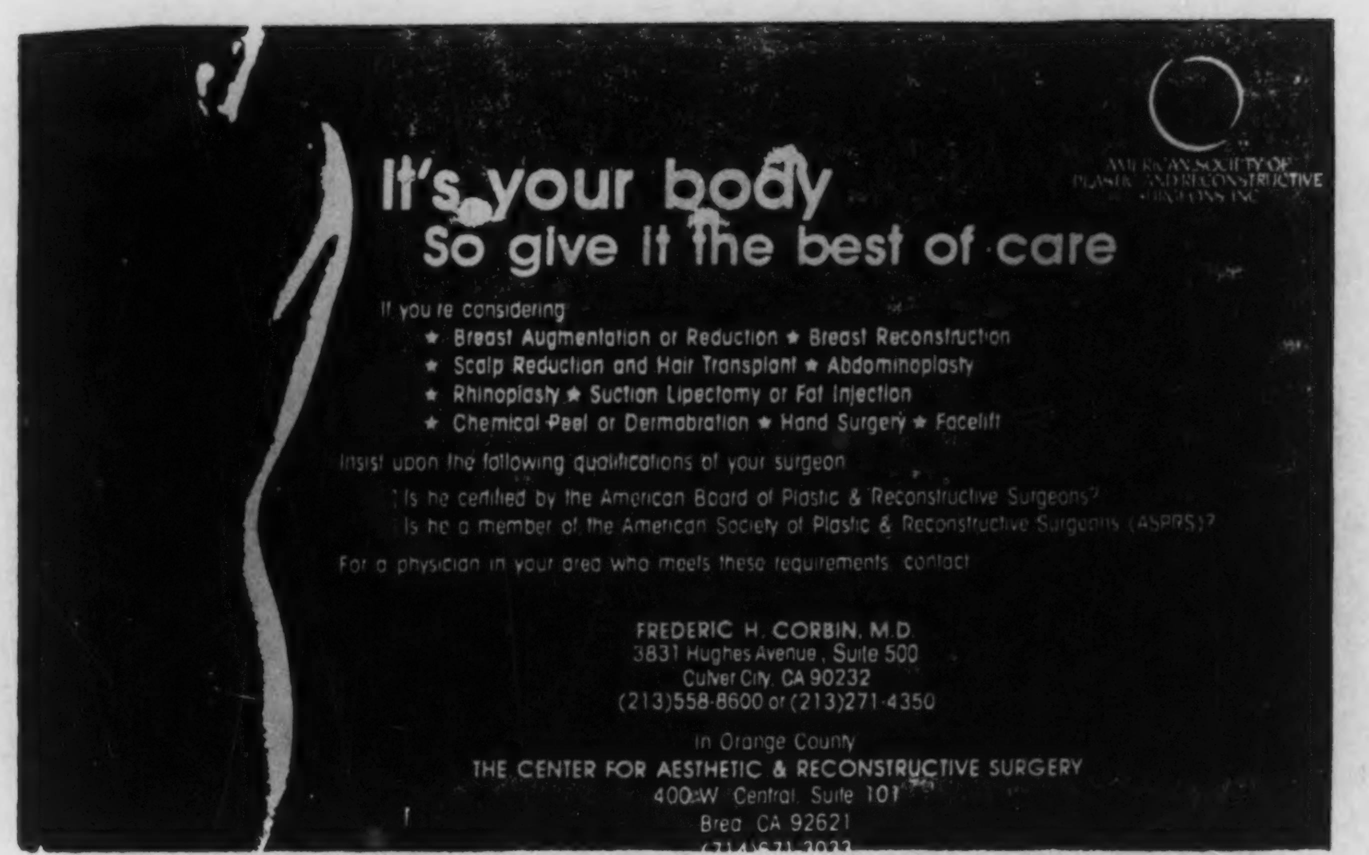

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The Six Most Important Questions to Ask When Considering Cosmetic Facial Surgery

*H*ow can you make the right decision when considering cosmetic facial surgery? Here are key questions you must answer before deciding, as suggested by *The Consumer's Guidebook to Cosmetic Facial Surgery*:

---

1. Are you a good candidate for cosmetic facial surgery? Many factors such as your general health, skin quality, life style and motivation must be considered. Only a consultation with an experienced, qualified specialist can help you determine your candidacy.

---

2. How specialized is your prospective doctor? Don't be shy about asking which procedures your prospective doctor specializes in or performs most frequently. A high degree of specialization is extremely important. Ask to see the doctor's professional biography. Some additional credentials to check include board certification, additional "fellowship" training exclusively in cosmetic facial surgery, and teaching and research responsibilities.

. What should you expect from your consultation? The purpose of the consultation is for you to learn and to have your questions answered completely. Your meeting with the doctor should be unhurried, relaxed and comfortable. Books and other reading material should be available to you. Learn as much as you can. The more informed you are, the better your decision will be. It's a matter of being a smart consumer.

---

4. What results can I expect? Before and after photographs of a variety of patients should be available to you. These can give you a sense of the doctor's artistry. Of course, the best results look natural. It also helps to meet or speak with people who have had the same procedure that you are considering. You can often better understand the process, expectations, and results through the experience of others.

Therefore, fees vary with each individual. You need to know the exact fee, what is included in the fee, and what payment options, including *financing*, are available. Some procedures may be eligible for insurance benefits.

---

6. How long is recovery? Most cosmetic facial surgery is now done in office facilities—on a "same day" basis. Hospitalization is usually not necessary. A "hideaway retreat" should be available if you want to recover away from home. Returning to work and normal activities is often surprisingly prompt. For example, after nasal surgery, most people return to work in one week.

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About Face is now available to you. This fifteen minute video features personal interviews with seven patients. These men and women discuss their entire experience. They share with you their feelings about results, costs, recovery, and most importantly—how they feel about themselves. You will see their befores and afters showing nasal surgery, face and neck lifting, non-surgical wrinkle removal, and neck and chin sculpturing. With your video, you'll also receive *The Consumer's Guidebook to Cosmetic Facial Surgery*; it includes a 19 point checklist you can use during your consultation.

Here are some of the people you will meet in *About Face*

Carolyn Neff 55 —"I'm a registered nurse and have been for 10 years. I've worked with lots of cosmetic surgeons . . . I feel so good about having done it myself."

Brian King, 27— "When I was young, I was always being made fun of and kidded about my nose . . . And now I can honestly say I feel better and I look better."

Joan Richards 49— "I had terrible wrinkles. There's a 100% difference now in how I feel. I go out and I look good, and that makes me feel good, too."

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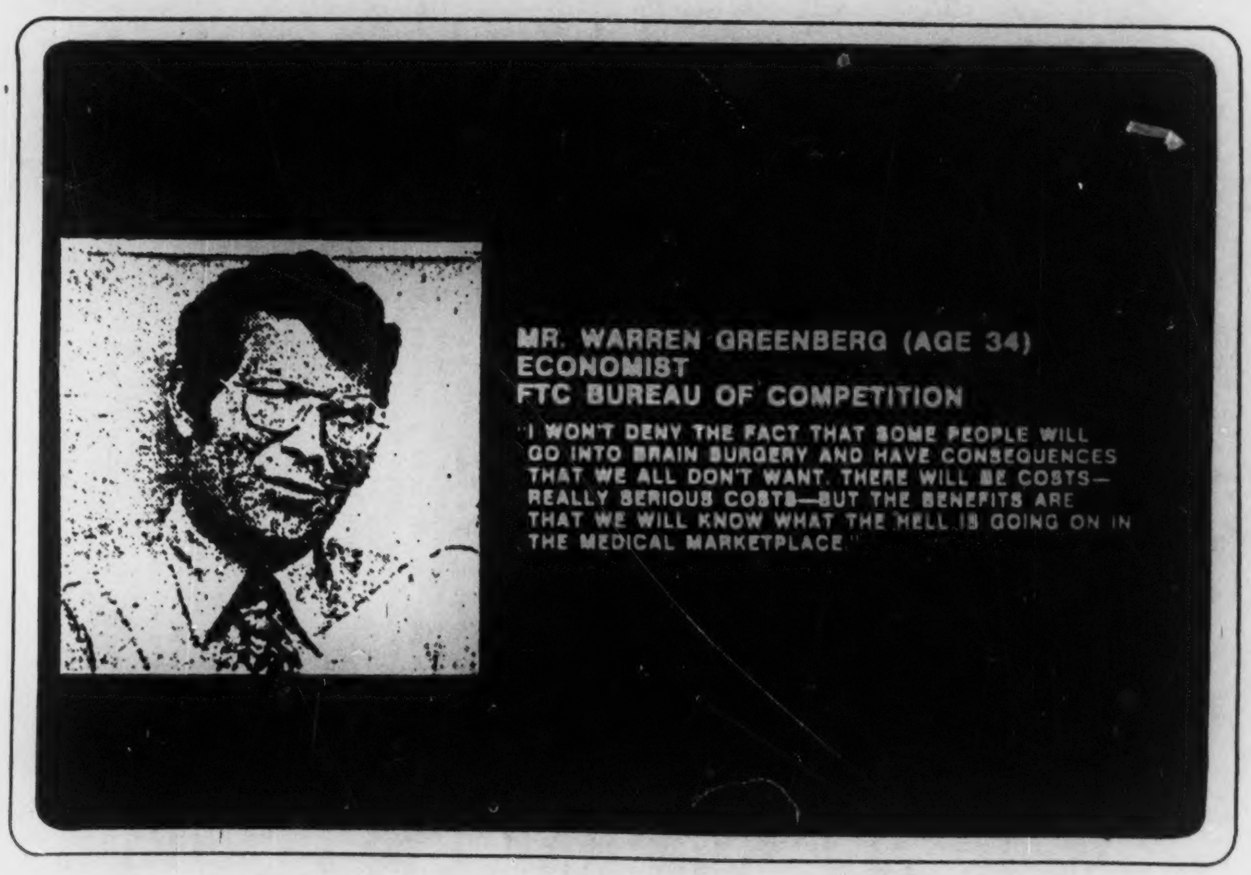
Name ______________________________

Address ______________________________

City ______________ State ______ Zip ______

Phone ______________________________



MR. WARREN GREENBERG (AGE 34)
ECONOMIST
FTC BUREAU OF COMPETITION

"I WON'T DENY THE FACT THAT SOME PEOPLE WILL GO INTO BRAIN SURGERY AND HAVE CONSEQUENCES THAT WE ALL DON'T WANT. THERE WILL BE COSTS—REALLY SERIOUS COSTS—BUT THE BENEFITS ARE THAT WE WILL KNOW WHAT THE HELL IS GOING ON IN THE MEDICAL MARKETPLACE."

Statement by F.T.C. theoretician to the medical press - 1977.

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF
THE CHAIRMAN

April 7, 1989

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation
Business Opportunities, and Energy
Committee on Small Business
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Wyden:

This is in further response to your letter dated March 20, 1989, in which you requested that the Commission prepare a list of actions -- both public and nonpublic -- that have been initiated by the FTC to review and correct potentially false and deceptive advertising by those in the medical profession, and in particular, by physicians practicing cosmetic procedures. Additionally, you asked that the compilation describe the current status of each activity and that Subcommittee staff be briefed on these activities.[1] The Commission hereby grants your requests for the requested list of actions as well as for staff briefings as an official request of a Congressional Subcommittee. See 5 U.S.C. § 552(d); Commission Rule 4.11(b), 16 C.F.R. § 4.11(b) (1988).

To provide the information requested by your letter, Commission staff conducted a computer search for all matters involving medical professionals or health care. After the initial computer search, obviously non-responsive matters were deleted and the remaining matters were then referred to the appropriate offices, either at headquarters or in the regions, for confirmation of relevance to a medical professional or to cosmetic procedures.

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[1] Pursuant to a March 23, 1989 discussion between Subcommittee staff members, Frank Papineau and D.Ann Murphy, and the Commission's Director of Congressional Relations, Craig Brightup, concerning the scope of this request, the Commission is providing a list of actions that were initiated starting in January 1975. This list includes competition matters that affect advertising by medical professionals, as well as consumer protection matters that deal with deceptive advertising.

The information responsive to your request for a list of actions is appended to this letter in the form of a chart. The chart lists all court and administrative cases, consent agreements and orders, competition advocacy comments, and investigations that involve FTC action to review and correct potentially false and deceptive advertising by those in the medical profession. The chart sets forth the name, file number, and current status of each of these FTC actions. Consumer protection and competition actions, as well as advocacy comments, are presented separately.

The chart contains both nonpublic and publicly available information. Information concerning court cases, Commission decisions, consent agreements, Commission orders, and filed advocacy comments is publicly available. Information concerning pending investigations and other nonpublic activities is protected from mandatory public disclosure under the FOIA. 5 U.S.C. § 552. Specifically, any staff recommendations included in the chart are protected from mandatory public disclosure under FOIA Exemption 5, 5 U.S.C. § 552(b)(5), as predecisional, deliberative material. NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 (1975); Coastal States Gas Corp. v. Department of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980). In addition, information about pending investigations would also be protected under FOIA Exemption 7(A), 5 U.S.C. § 552(b)(7)(A), because disclosure of this information could reasonably be expected to interfere with law enforcement proceedings. See NLRB v. Robbins Tire & Rubber Co., 437 U.S. 214 (1978).

The Commission anticipates that portions of the information that will be disclosed in the briefing will be derived from documents that are exempt from mandatory public disclosure under the FOIA. Some of the information that is likely to be conveyed in the briefing is based on internal staff memoranda that reveal information provided by submitters either pursuant to compulsory process or voluntarily in lieu thereof in a Commission law enforcement investigation. Section 21(f) of the FTC Act, 15 U.S.C. § 57b-2(f), exempts from mandatory public disclosure information received pursuant to compulsory process or voluntarily in lieu thereof in a law enforcement investigation. Therefore, information of this kind is protected from mandatory public disclosure by FOIA Exemption 3(B), 5 U.S.C. § 552(b)(3)(B), by virtue of Section 21(f) of the FTC Act, 15 U.S.C. § 57b-2(f). McDermott v. FTC, 1981-1 Trade Cas. (CCH) ¶ 63,964 at 75,982 (D.D.C. 1981); Dairymen, Inc. v. FTC, 1980-2 Trade Cas. (CCH) ¶ 63,479 at 76,510 (D.D.C. July 9, 1980).

In addition to the protection afforded by FOIA Exemption 3, the briefing could divulge information submitted by medical professionals or other parties that may be protected under Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FOIA

Exemption 4, 5 U.S.C. § 552(b)(4), as confidential commercial or financial information the public disclosure of which could result in substantial competitive harm to the submitter. See National Parks & Conservation Ass'n v. Morton, 498 F.2d 765 (D.C. Cir. 1974). Because these medical professionals may still compete as providers of medical services, disclosure of information about their competitive situations could result in substantial competitive harm to them.

Further, the briefing is likely to involve the disclosure of information from documents that may be protected under FOIA Exemption 5, 5 U.S.C. § 552(b)(5), as attorney work product prepared in anticipation of litigation. FTC v. Grolier, Inc., 462 U.S. 19, 28 (1983); Martin v. Office of Special Counsel, Merit Systems Protection Board, 819 F.2d 1181, 1187 (D.C. Cir. 1987). Some of this information may also be protected from mandatory public disclosure by FOIA Exemption 5 because it is derived from intra-agency predecisional, deliberative material and thus reflects internal analyses, opinions, and recommendations that were part of the decisionmaking process in the underlying matters. NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 (1975); Coastal States Gas Corp. v. Department of Energy, 617 F.2d 854, 866 (D.C. Cir. 1980).

The Commission also notes that some of the information likely to be discussed in the briefing may have been obtained from confidential sources, e.g., physician complainants. Disclosure of information of this kind could reasonably be expected to reveal the identities of confidential sources and therefore would be exempt from mandatory public disclosure under FOIA Exemption 7(D), 5 U.S.C. § 552(b)(7)(D). See, e.g., Brant Constr. Co. v. EPA, 778 F.2d 1258, 1263-65 (7th Cir. 1985); Miller v. Bell, 661 F.2d 623, 627-28 (7th Cir. 1981), cert. denied sub nom. Miller v. Webster, 456 U.S. 960 (1982); Mobil Oil Corp. v. FTC, Civil No. 74-CIV-311, Slip Op. at 3 (S.D.N.Y. Dec. 7, 1978) (unsolicited complaints).

Notwithstanding the exempt status of some of the responsive information, the FOIA is not authority to withhold this information from Congress, 5 U.S.C. § 552(d), and the Commission has determined to provide this information to you. Because much of the information provided is not available to the public under FOIA or otherwise, the Commission respectfully requests that the Subcommittee maintain the confidentiality of the exempt information disclosed on the list and in the staff briefings.

Your letter requesting this information states that you are concerned that Commission enforcement of the antitrust laws in the health care field has injured consumers by leading to an increase in false and deceptive advertising by physicians. You also note that "some believe" that advertising by physicians has caused a deterioration in the quality of medical care. The Commission looks forward to addressing your concerns during the hearings, because, as we can explain in more detail at that time, we believe that our activities have benefitted, rather than injured, consumers.

By direction of the Commission.

Daniel Oliver
Chairman

COMPETITION MATTERS

FINAL ORDERS

	NUMBER	NAME	CURRENT STATUS
1.	C 3193	American Academy of Optometry	consent order
2.	D 9093	American Dental Association	consent order ongoing compliance investigation
3.	D 9064	American Medical Association	litigated order ongoing compliance investigation
4.	C 3097	Association of Independent Dentists	consent order
5.	C 3091	Broward County Medical Association	consent order
6.	D 9188	Louisiana State Board of Dentistry	consent order
7.	D 9195	Massachusetts Board of Registration in Optometry	litigated order
8.	C 3112	Michigan Association of Osteopathic Physicians and Surgeons	consent order ongoing compliance investigation
9.	C 3170	Michigan Optometric Association	consent order
10.	C 3161	Montana Board of Optometrists	consent order (BCP)
11.	D 9191	Oklahoma Optometric Association	consent order
12.	C 3219	Tarrant County Medical Society	consent order
13.	C 3118	Washington, D.C. Dermatological Society	consent order
14.	C 3221	Wyoming State Board of Chiropractic Examiners	consent order
15.	C 3176	Wyoming State Board of Registration in Podiatry	consent order (BCP)

BC CLOSED INVESTIGATIONS

	NUMBER	NAME	CURRENT STATUS
16.	8710100	Alabama Optometric Association	closed
17.	8610067	Alaska State Board of Chiropractic Examiners	closed
18.	8710038	American Association of Orthodontists	closed
19.	8510130	American Osteopathic Association	closed
20.	8410046	Arizona State Board of Pharmacy	closed
21.	8610128	Arkansas Chiropractic Board	closed
22.	8510175	Arkansas State Board of Dental Examiners	closed
23.	8510083	Arkansas State Podiatry Examining Board	closed
24.	8510045	Board of Chiropractic Examiners of Oklahoma	closed
25.	8810053	Colorado Vision Services, Inc.	closed
26.	8510012	Georgia State Board of Pharmacy	closed
27.	8410045	Idaho State Board of Pharmacy	closed
28.	8510069	Idaho State Board of Podiatry	closed
29.	8610013	Kentucky Medical Association	closed
30.	8610043	Kentucky Board of Dentistry	closed
31.	8410044	Louisiana Board of Pharmacy	closed
32.	8910041	Maryland Podiatry Board	closed

33.	8510011	Massachusetts Board of Registration in Medicine	closed
34.	8410202	Medical Licensing Board of Indiana	closed
35.	8410210	Medical Licensing Board of Missouri	closed
36.	8510096	Medical Society of Milwaukee County	closed
37.	8310150	Medical Society of the State of New York	closed
38.	8510089	Michigan Board of Pharmacy	closed
39.	8410108	Minnesota Dentistry Board	closed FTC advocacy comments filed
40.	8410043	Minnesota State Board of Pharmacy	closed
41.	8410213	Mississippi State Board of Dental Examiners	closed
42.	8710034	Montana Board of Dentistry	closed
43.	8610153	National Federation of Clinical Social Workers	closed
44.	8510141	Nevada State Board of Pharmacy	closed
45.	8610129	New Mexico State Board of Chiropractic Examiners	closed
46.	8510099	North Carolina State Board of Dental Examiners	closed
47.	8710091	Optometric Society of Greater Kansas City	closed
48.	8610066	Oregon State Board of Chiropractic Examiners	closed
49.	8610058	Oregon State Board of Clinical Social Workers	closed
50.	8810119	Pennsylvania State Board of Optometry	closed

51.	8810125	Pennsylvania State Board of Dentistry	closed FTC advocacy comments being prepared
52.	8310088	San Antonio District Dental Society	closed
53.	8110100	San Diego County Dental Society	closed
54.	8510088	Wisconsin Dentistry Examining Board	closed
55.	8410211	Wisconsin Medical Examining Board	closed
56.		Advisory Opinion: American Academy of Ophthalmology	

BC OPEN INVESTIGATIONS

	NUMBER	NAME	CURRENT STATUS
57.	8810085	American Academy of Ophthalmology	ongoing
58.	8610082	American Psychological Association	ongoing
59.	8910068	Arizona Board of Optometry	ongoing
60.	8510161	California Dental Association	ongoing
61.	8710027	Colegio de Cirujanos Dentistas de Puerto Rico	ongoing
62.	8410126	Colorado State Board of Pharmacy	ongoing
63.	8810134	Connecticut Chiropractic Association	ongoing
64.	8810066	Florida Board of Dentistry	ongoing
65.	8810072	Indiana State Board of Dentistry	ongoing
66.	8910033	Maine Board of Chiropractic Examiners	ongoing
67.	8510145	Massachusetts Board of Registration in Pharmacy	ongoing
68.	8910034	Massachusetts Board of Registration in Podiatry	ongoing
69.	8610126	National Association of Social Workers	ongoing consent order signed Bureau reviewing
70.	8810049	New Jersey Board of Dentistry	ongoing
71.	8810048	New Jersey Board of Optometry	ongoing
72.	8810061	New Nexico Board of Dentistry	ongoing
73.	8810124	South Carolina State Board of Dentistry	ongoing

74.	8710025	Texas Board of Chiropractic Examiners	Commission voted to place consent order on public record
75.	8810031	Texas State Board of Podiatry Examiners	ongoing

BCP CLOSED INVESTIGATIONS

	NUMBER	NAME	CURRENT STATUS
76.	8523097	Florida Board of Podiatry	closed
77.	8423203	Georgia Board of Dispensing Opticians	closed
78.	8423121	Georgia Board of Optometry	closed
79.	8423204	Iowa Board of Dental Examiners	closed
80.	8523098	Kansas State Dental Board	closed
81.	8423127	Maryland Board of Dentistry	closed
82.	8523096	Mississippi Optometry Board	closed
83.	8423117	New Hampshire Board of Podiatry	closed
84.	8423275	North Carolina Board of Optometry	closed
85.	8423124	North Dakota Board of Optometry	closed
86.	8523123	North Dakota Dental Board	closed
87.	8423120	Ohio Board of Dental Examiners	closed
88.	8423154	Pennsylvania Board of Podiatry Examiners	closed
89.	8423002	South Carolina Board of Optometry	closed
90.	8523134	Tennessee Board of Dentistry	closed
91.	8423118	Virginia Board of Dentistry	closed

CONSUMER PROTECTION MATTERS
FINAL ORDERS

NUMBER	NAME	CURRENT STATUS
1. D8996	Simeon Management Corp.	Closed; Litigated Order
2. 832-3243	Hair Analysis Laboratories, et al.	Closed; Spin-off Litigated Order
	-- A&A Laboratories, and Arthur J. Furman, D.D.S.	
3. C2648	Miriam Maschek, Inc.	Closed; Consent Order
4. C3013	Hair Extension of Beverly Hills, Inc.	Closed; Consent Order
5. C3031	Terrance D. Lesko, M.D.	Closed; Consent Order
6. 792-3023	Acne Product Mfrs., Unnamed	Closed; Spin-off Consent Orders (San-Mar, AHC, Hayoun, Harvey Glass, M.D.)
7. D9109	Karr Preventative Medical Products	Closed; Consent Order
8. C3003	San-Mar Laboratories, Inc.	Closed; Consent Order
9. C3017	AHC Pharmacal, Inc.	Closed; Consent Order
10. C3019	Hayoun Cosmetique, Inc.	Closed; Consent Order
11. C3004	Harvey Glass, M.D.	Closed; Consent Order
12. 822-3165	Laser Biostimulation Advertisers	Closed; Spin-off Consent Order
C3122	Spinal Health Services, Inc., et al.	
13. D9194	Buckingham Productions, Inc., et al.	Closed; Consent Order

CONSUMER PROTECTION MATTERS
RULES ISSUED

NUMBER	NAME	CURRENT STATUS
14. R611003	Ophthalmic Goods and Services	Rule Issued; Eyes I
15. R011136	Ophthalmic Practice Rules	Rule Issued; Eyes II

CONSUMER PROTECTION MATTERS
CLOSED

NUMBER	NAME	CURRENT STATUS
16. 792-3081	Unnamed Plastic Surgeons	Closed
17. 832-3018	World Institute of Health, Inc.	Closed
18. 842-3175	Immuvita, Inc., et al.	Closed
19. 842-3245	Raleigh Hills Hospitals	Closed
20. 842-3234	Chelation Therapy, Sellers	Closed
21. 852-3092	Institute of Medical Research	Closed
22. 852-3110	Arlin J. Brown	Closed
23. P854907	Manual for Health Care Advertising	Closed
24. 852-3253	Mehl Int'l Corp.	Closed
25. 852-3272	Chelation Therapy	Closed
26. P868801	Regional Health Fraud Conference (NYRO)	Closed
27. 862-3056	Beverly Hills Rejuvenation Medical Corp.	Closed
28. 862-3124	Alfin Fragrances, Inc.	Closed
29. 872-3136	Total Health Plan, Inc.	Closed
30. 862-3159	First Hospital Corp.	Closed
31. 872-3080	Weisser Eye Care	Closed

CONSUMER PROTECTION MATTERS
ONGOING

32.	852-3292	National Iridology Assoc.	Ongoing
33.	842-3176	Optometric Services	Ongoing
34.	842-3261	Health Care Services, Marketers of	Ongoing
35.	P858810	Health Fraud	Ongoing (NYRO)
36.	872-3191	Pantron I Corp.	Ongoing Litigation
37.	P874918	Prof. Advertising -- Health Care Fraud	Ongoing
38.	882-3167 (X890013)	California Pacific Research	Ongoing Litigation
39.	882-3203 (X90014)	Cecil B. Jacobson, M.D.	Ongoing Litigation
40.	882-3199	Twin Star Productions, Inc.	Ongoing
41.	892-3120	Center for Human Reproduction	Ongoing
42.	892-3112	Medical Marketing Services	Ongoing
43.	892-3133	Union Memorial Hospital	Ongoing
44.	P894909	Providers of Health Care Infertility Services	Ongoing
45.	P894907	Cosmetic Surgery Advertising	Ongoing
46.	892-3138	Vincent R. Forshan, M.D.	Ongoing
? 47.	(Pending)	Smooth Line	Ongoing

Michael

ADVOCACY COMMENTS FILED BY FEDERAL TRADE COMMISSION STAFF CONCERNING ADVERTISING REGULATION OF HEALTH CARE PROFESSIONALS 1975 - Present

Prepared by the Office of Consumer and Competition Advocacy
April 3, 1989

NUMBER	PROJECT NUMBER	NAME	CURRENT STATUS (COMMENT FILED)
1.	I-258307	Entrepreneurial Trends in Health Care Delivery: The Development of Retail Dentistry and Freestanding Ambulatory Services Study by Institute for Health Policy Studies of the University of California	July 1982
2.	I-408321	Testimony of the San Francisco Regional Office (RO) before the California State Assembly Sacramento, CA	June 28, 1983
3.	I-398322	Testimony of Ronald Bond before the Health Committee of the California State Assembly Sacramento, CA	May 10, 1983
4.	I-538335	Testimony of the San Francisco RO before the Senate Business and Professions Committee of the California State Legislature Sacramento, CA	May 9, 1983
5.	I-1238461	Letter to Alan Tresidder, Legislative Research Office, Legislative Administration Committee Salem, OR	August 31, 1984
6.	I-1208458	Letter to Richard Morrison, Dept. of Health Regulatory Bds. Richmond, VA	August 21, 1984
7.	I-1258463	Letter to Richard Morrison, Dept. of Health Regulatory Bds Richmond, VA	September 14, 1984
8.		Letter to James Hickey, New Hampshire Board of Registration in Podiatry Concord, New Hampshire	January 17, 1985

NUMBER	PROJECT NUMBER	NAME	CURRENT STATUS (COMMENT FILED)
9.	P 854624	Letter to E.E. Tuhy, President, North Dakota State Bd. of Optometry Carrington, ND	February 14, 1985
10.	P 854634	Letter to Robert Siconolfi, Exec. Secretary, New Jersey State Bd. of Dentistry Newark, NJ	March 19, 1985
11.	P 854649	Hon. Ralph Axselle, Governor's Regulatory Reform Bd. Richmond, VA	May 22, 1985
12.	P 854652	Letter to Stephen Tanzer, Legislative Council of Delaware Dover, Delaware	May 31, 1985
13.	P 854660	William Hohenberger, Dept. of Health, Office of Hearings Baltimore, MD	
14.	P 854684	Letter to Dale Forseth, Minn. Bd. of Dentistry Minneapolis, Minn	September 23, 1985
15.	P 864603	Letter to George Sanchez, Arizona State Bd. of Optometry Phoenix, Ariz	October 17, 1985
16.	P 864607	Letter to Leonard Morse, Mass. Board of Registration in Medicine Boston, MA	October 30, 1985
17.	P 844615	Letter to Hon. Peter Sullivan, Assemblyman, New York Assembly Albany, NY	December 18, 1985
18.	P 864632	Testimony Before the Committee on Regulatory Reform, Florida House of Representatives Tallahassee, FL	April 30, 1986
19.	P 844640	Letter to Nancy T. Feldman, Exec. Dir., Va. State Bd. of Dentistry Richmond, VA	April 3, 1986

NUMBER	PROJECT NUMBER	NAME	CURRENT STATUS (COMMENT FILED)
20.	P 864642	Letter to Moira Lux, Exec. Dir., Va. State Bd. of Optometry Richmond, VA	April 15, 1986
21.	P 844651	Letter to Hon. John McNeil, House of Rep., State House Boston, MA	June 10, 1986
22.	P 864657	Omar P. Whisman, Exec. Dir., Ohio State Dental Board Columbus, Ohio	June 18, 1986
23.	P 864658	Eric Muir, President, Miss. State Bd. of Optometry Cleveland, Miss	July 10, 1986
24.	P 864662	U.S. Court of Appeals for the Sixth Circuit Parker v. Commonwealth of Kentucky Amicus Brief	August 16, 1986
25.	P 844663	Owen Yamasaki, Office of the Auditor Honolulu, HA	August 21, 1986
26.	P 874627	Letter to David Garcia, Esq., Office of the Attorney General, State of New Mexico Santa Fe, New Mexico	January 7, 1987
27.	P 874615	Letter to R.B. Thompson, Executive Director, Kentucky Board of Dentistry Louisville, Ky	March 21, 1986
28.	P 874616	Letter to David Garcia, Esq., Office of the Attorney General, State of New Mexico Santa Fe, NM	December 4, 1986
29.	P 874637	George L. Schroeder, Legislative Audit Council Columbia, SC	February 19, 1987
30.	P 874660	C.D. Lunsford, Georgia State Auditor's Office Atlanta, GA	April 2, 1987
31.	P 874670	Gwen Mathews, Executive Director, Florida Board of Dentistry Tallahassee, FL	April 23, 1987

NUMBER	PROJECT NUMBER	NAME	CURRENT STATUS (COMMENT FILED)
32.	P 874671	Nancy T. Feldman, Virginia State Board of Dentistry Richmond, VA	April 23, 1987
33.	P 874673	George L. Schroeder, Legislative Audit Council, State of South Carolina Columbia, SC	April 23, 1987
34.	P 874677	Dr. William A. Overton, President, Tennessee Board of Dentistry Nashville, TN	April 30, 1987
35.	P 874678	Honorable Harry Hill, State Representative, State Capitol Jefferson City, MO	May 13, 1987
36.	V870011	Senator Gerry Hinton, Louisiana State Senate Baton Rouge, LA	June 25, 1987
37.	V870017	William Gutman, Executive Secretary, New Jersey State Board of Dentistry Newark, NJ	July 14, 1987
38.	V880006	Dorothy Hodgson, Chairman, Idaho State Board of Chiropractic Physicians Boise, Idaho	December 7, 1987
39.	V880025	Dr. Robert Rector, President, Montana Board of Dentistry Helena, MT	May 3, 1988
40.	V890033	Proposed Comment to Frank Ertz, Executive Director, Independent Regulatory Review Commission, Commonwealth of Pennsylvania Harrisburg, PA	Comment under consideration.
41.	V890042	Proposed Comment to Oklahoma Medical Board Oklahoma City, OK	Comment under consideration.

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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

TARRANT COUNTY MEDICAL SOCIETY,
a corporation.

Docket No. C-3219

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended (Title 15, U.S.C. § 41 et seq.), and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that the named respondent has violated the provisions of Section 5 of the Federal Trade Commission Act and that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint, stating its charges as follows:

PARAGRAPH ONE: Respondent Tarrant County Medical Society is a corporation formed pursuant to the laws of the State of Texas, with its mailing address at 3855 Tulsa Way, Fort Worth, Texas 76107.

PARAGRAPH TWO: Respondent is a professional association formed to represent the interests of physicians who practice in Tarrant County, Texas. Respondent has approximately 1,300 members, constituting a substantial majority of the physicians in Tarrant County.

PARAGRAPH THREE: Respondent is a component society of the Texas Medical Association, which in turn is a constituent society of the American Medical Association.

PARAGRAPH FOUR: Members of respondent are engaged in the business of providing medical health care services for a fee. Except to the extent that competition has been restrained as herein alleged, members of respondent have been and are now in competition among themselves and with other physicians.

PARAGRAPH FIVE: Respondent engages in substantial activities which further its members' pecuniary interests. By virtue of its purposes and activities, respondent is a corporation within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

PARAGRAPH SIX: In the conduct of their business, members of respondent receive substantial sums of money, which flow across state lines, from the federal government and from private insurers for rendering medical services, and purchase equipment and supplies and prescribe medicines which are shipped in interstate commerce. The acts or practices described below are in interstate commerce, or affect the interstate activities of respondent's members, third-parties who pay for medical services, other third parties, and some patients of respondent's members, and are in or affect commerce within the meaning of Section 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1).

PARAGRAPH SEVEN: Respondent has acted as a combination of at least some of its members or has conspired with at least some of its members to hinder, frustrate, or restrict competition among physicians in Tarrant County by restricting or attempting to restrict its members from disseminating information to consumers through truthful, non-deceptive advertising.

PARAGRAPH EIGHT: Respondent has engaged in various acts and practices in furtherance of this combination or conspiracy, including:

A. Through its Board of Censors, restricting or attempting to restrict the amount, duration, and size of advertising announcements that members place in newspapers. For example, respondent distributed restrictions to members that limit advertising announcements in newspapers to ten days and one-column inch in size; and

B. Through its Board of Censors, restricting or attempting to restrict the number of telephone directory listings its members place and the size of their print.

PARAGRAPH NINE: The purposes or effects of the combination or conspiracy and acts or practices of respondent as described above have been and are to unreasonably restrain competition and injure consumers in one or more of the following ways, among others:

A. Vigorous competition among physicians is impeded;

B. Physicians are being deterred from advertising truthful information in the media about their prices, services, and qualifications; and

C. Consumers are being deprived of receiving truthful information about physicians' prices, services, and qualifications.

PARAGRAPH TEN: The combination or conspiracy and the acts and practices described above constitute unfair methods of competition and unfair acts or practices which violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination or conspiracy is continuing and will continue absent the entry against respondent of appropriate relief.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission, on this 2nd day of November, 1987, issues its complaint against the Tarrant County Medical Society.

By the Commission.

SEAL

Emily H. Rock

Emily H. Rock
Secretary

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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Daniel Oliver, Chairman
Patricia P. Bailey
Terry Calvani
Mary L. Azcuenaga
Andrew J. Strenio, Jr.

In the Matter of TARRANT COUNTY MEDICAL SOCIETY, a corporation.	DOCKET NO. C-3219 DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent Tarrant County Medical Society (TCMS), and TCMS having been furnished thereafter with a copy of a draft of complaint which the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

TCMS, its duly authorized officer, its attorney, and counsel for the Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedures prescribed in §2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. TCMS is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its mailing address at 3855 Tulsa Way, Fort Worth, Texas 76107.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I.

For purposes of this order, the following definitions shall apply:

A. "TCMS" means respondent Tarrant County Medical Society, its officers, councils, committees, boards, representatives, agents, employees, successors, and assigns; and

B. "Adverse action" means the revocation or suspension of, or refusal to grant, membership in TCMS, or the disciplining or penalizing of any physician.

II.

IT IS ORDERED, that TCMS, directly or indirectly, or through any device, shall forthwith cease and desist from:

Restricting, regulating, declaring unethical, impeding, interfering with, or advising against the advertising or publishing by any person or organization of information about the prices, terms, or conditions of sale of physicians' services, or of any information about physicians' services, facilities, or equipment which are offered for sale or made available by physicians or by any organization with which physicians are affiliated, including but not limited to restricting or attempting to restrict the content, format, size, or frequency of any such advertisements or publications.

Nothing contained in this order shall prohibit TCMS from formulating, adopting, disseminating to its members, and enforcing reasonable ethical guidelines governing the conduct of its members with respect to representations, including unsubstantiated representations, that TCMS reasonably believes would be false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act.

III.

IT IS FURTHER ORDERED, that TCMS shall cease and desist from:

A. For a period of ten (10) years after service of this order, taking any adverse action against a person alleged to have violated any rule, policy, guideline, or ethical standard relating to physician advertising without first providing such person with written notice of the allegations against such person and without providing such person a reasonable opportunity to respond. The notice required by this part shall, at a minimum, clearly specify the rule, policy, guideline, or ethical standard alleged to have been violated, the specific conduct that is alleged to have violated the rule, policy, guideline, or ethical standard, and the reasons the conduct is alleged to have violated the rule, policy, guideline, or ethical standard; and

B. Failing to maintain for five (5) years following the taking of any action referred to in this part of the order, in a separate file segregated by the name of any person against whom such action was taken, any document that embodies, discusses, mentions, refers, or relates to the action taken and any allegation relating to it.

IV.

IT IS FURTHER ORDERED, that TCMS shall:

A. For a period of five (5) years, commencing on the date this order is served, provide each applicant for membership in TCMS with a copy of this order at the time the applicant applies for membership;

B. Within sixty (60) days after service of this order, publish a copy of the complaint and this order in the Physician, or in any successor publication, with the same prominence as regularly published feature articles;

C. Within fifteen (15) days after service of this order, remove from TCMS' documents entitled "Board of Censors Agenda for Meeting with Provisional Members" and "Board of Censors Meeting with Applicants for Membership," and any other existing ethical or policy statement or guideline of TCMS, any provision, interpretation or statement which is inconsistent with Part II of this order, and within sixty (60) days after service of this order, publish, in the manner described in Part IV.B. of this order, a copy of the revised versions of such statements, guidelines, or interpretations to each of its members;

D. Within sixty (60) days after service of this order, send to the Southwest Bell Telephone Company supervisor in charge of professional advertising a copy of this order and accompanying complaint;

E. Within ninety (90) days after service of this order, and at any time the Commission, by written notice, may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which TCMS has complied with this order; and

F. For a period of five (5) years after service of this order, maintain and make available to the Commission staff for inspection and copying upon reasonable notice, records adequate to describe in detail any action taken in connection with the activities covered by Parts II and III of this order, including but not limited to any advice or interpretation rendered with respect to advertising involving any physician.

V.

IT IS FURTHER ORDERED, that TCMS shall notify the Commission at least thirty (30) days prior to any proposed change in the respondent, such as dissolution or reorganization resulting in the emergence of a successor corporation or association, or any other change in the corporation or association which may affect compliance obligations arising out of this order.

By the Commission.

Emily H. Rock

[Seal]

Emily H. Rock
Secretary

ISSUED: November 2, 1987

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

BUREAU OF
CONSUMER PROTECTION

April 23,1987

Nancy T. Feldman
Executive Director
Virginia State Board of Dentistry
1601 Rolling Hills Drive
Richmond, VA 23229

Dear Mrs. Feldman:

The staff of the Federal Trade Commission[1] is pleased to respond to your notice requesting public comment on final regulations proposed by the Virginia Board of Dentistry ("Board"). We agree with many of the contemplated regulatory changes, but also believe that some further amendments are appropriate.

As you know, we have submitted comments in each of the last three years concerning existing and proposed laws and regulations governing the practice of dentistry in Virginia.[2] Those comments urged the Board of Dentistry to remove or recommend the elimination of provisions that restrained nondeceptive advertising, the use of trade names, certain commercial forms of practice, and the operation of prepaid dental plans. The Board has now proposed new regulations that would eliminate many of the most troublesome advertising prohibitions. These changes would lift the existing bans on the advertising of statistical data, statements of past performance, representations of quality, the use of testimonials, and implied statements of specialization by general dentists. We applaud these changes because they will broaden the scope of useful information that dentists may advertise, and will thereby benefit consumers.

The Board still retains some regulations, however, unnecessarily inhibiting the offer of discounts and fee advertising for nonroutine services. These provisions, as well as those statutes that restrict the use of trade names, commercial forms of dental practice, and the operation of prepaid dental plans, may have significant adverse consequences for consumers of dental services but appear to provide no countervailing consumer benefits. We therefore again urge the Board to eliminate the proposed administrative rules limiting discount offers and fee advertising, and to recommend to the Legislature, at an appropriate time, the repeal or modification of the statutory restraints discussed below.

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[1] These comments represent the views of the FTC's Bureaus of Consumer Protection, Competition and Economics, and not necessarily those of the Commission itself. The Commission has, however, voted to authorize submission of these comments.

[2] Letter to Nancy T. Feldman from Amanda B. Pedersen, April 3, 1986; letter to Ralph Axselle from Carol T. Crawford, May 22, 1985; and letter to Richard Morrison from Carol T. Crawford, August 21, 1984. These comments, copies of which are attached, are incorporated by reference.

We are also taking this opportunity to comment on another proposed Board rule that appears to require the physical presence of a supervising dentist whenever dental services are provided by licensed hygienists. We comment on this rule now because the Virginia legislature just last year relaxed the required level of dentists' supervision of hygienists. Unnecessary restraints on dentists' ability to define the appropriate level of supervision may inhibit the efficient delivery of dental services, and thereby harm consumers. We therefore recommend that the Board implement last year's legislative amendment by adopting a more flexible standard of supervision than is now proposed.

Unnecessary restraints on the delivery of professional services are particularly important in the dental area because of the relatively high number of consumers who may not be receiving the dental services they need. A survey conducted by the National Center for Health Statistics found that in 1975 half of the U.S. population had not visited a dentist in a year, over one-third had not seen a dentist in two years or longer, and about 20 million Americans had never visited a dentist.[3] At the same time, a comprehensive survey of the dental health of Americans for the years 1971-1974 found that at least one-third and possibly as many as two-thirds of all Americans had unmet basic dental needs.[4] Over one-third of the population, for example, were found to have untreated decay in permanent teeth.[5]

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[3] National Center for Health Statistics, U.S. Dept. of Health, Education and Welfare (now the Department of Health and Human Services), Pub. No. (HRA) 77-1543, Current Estimates from the Health Interview Survey, United States, 1975 (1977).

[4] National Center for Health Statistics, U.S. Dept. of Health, Education and Welfare (now DHHS), Pub. No. (PHS) 79-1662, Basic Data on Dental Examination Findings of Persons 1-74 years, United States 1971-1974 (1979). These conclusions were based on dental examinations of a statistical sample (20,749 individuals) of the civilian, noninstitutionalized U. S. population.

[5] Id. at Table 9. Other dental needs identified by the survey included untreated tooth decay in 54% of children aged 12-17; the need for a full upper or lower denture or both in one-fourth of all Americans over the age of 65; untreated gum disease in one of every five Americans; and the need for partial dental appliances (footnote continued)

While these studies were conducted over a decade ago, they represent the most recent comprehensive documentation on the dental health of the U.S. population. The study results may therefore be indicative of the dental needs of Virginia consumers. A potential benefit of removing unnecessary restraints on the efficient delivery of dental services would be the provision of dental services to Virginia consumers who need but are not currently receiving them.[6] For this additional reason, we believe that the restraints discussed below should be removed.

Advertising Restrictions

The proposed final regulations still contain two provisions that we urged the Board to eliminate in our earlier comments and that we believe will reduce consumer welfare. First, rule 4.4.C. requires disclosure of the original price whenever a discount is advertised. Because it is impractical to state in an advertisement the regular prices of all the hundreds of services a dentist provides, this rule effectively bans all across-the-board discount advertising.[7] Discount advertising is not inherently deceptive, and can be of great benefit to consumers by increasing price competition among dentists.

While we recognize the potential for deceptive schemes in discount advertising, we believe that burdensome disclosures on such offers are overly restrictive and unnecessary. Virginia Code § 54-187(7) and proposed Board rule 4.4.F. already contain appropriate general prohibitions on untruthful or deceptive advertising claims. Any deceptive discount offers in advertising

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(fixed bridges or partial removable dentures) in about one-sixth of the population. Id.

[6] Several factors have been identified to explain why individuals are unable or unwilling to seek dental care routinely. Among them are: the high cost, both in terms of price and time of dental services; a lack of awareness of the consequences of untreated dental disease; and the fear of pain. See, e.g., Bureau of Health Manpower, U.S. Dep't. of Health, Education and Welfare (now DHHS), Factors Which Affect the Utilization of Dental Services, Pub. No. (HRA) 78-64 (1978). While we are not in a position to weigh the relative importance of these factors, we believe that the removal of any unnecessary restraint on the delivery of dental services can potentially benefit consumers by increasing the availability of those services.

[7] It should be noted that at least one court has invalidated on First Amendment grounds similar requirements that advertisements for discounted prices include all regular non-discounted prices. South Ogden CVS Store v. Ambach, 493 F. Supp. 374 (S.D. N.Y. 1980).

would therefore be proscribed under current law.

Second, proposed rule 4.4.E. limits fee advertising to certain listed and defined routine dental services. We discussed the potentially harmful effects of this rule when it was first proposed as rule 4.6.E., and we incorporate those comments by reference now. (Letter to Mr. Axselle at pp. 11-12). We believe that this rule needlessly inhibits fee advertising for new or innovative techniques and requires the use of specific scientific terminology that will be confusing to lay consumers. We can envision no consumer benefit from such a restriction.

Finally, we again urge the Board to seek the repeal of Virginia Code §54-187(7), which bans claims of superiority. This provision appears to prohibit the advertising of much useful and nondeceptive information about dentists' practice, qualifications, experience or performance. In the interim, we again urge the Board to interpret this provision to permit the greatest possible amount of nondeceptive advertising that is consistent with the statute.

Trade Name Restriction

Section 54-184 of the Virginia Code prohibits dentists from practicing under a trade name. We understand that the Board recommends no changes to this statutory provision. As we discussed in our earlier comments, trade names can lead to significant benefits for consumers of dental services, as they do in markets for other goods and services. Moreover, we believe that the goal of professional accountability can be better accomplished by requiring the conspicuous posting of individual practitioners' names at offices where they provide services, or requiring that they be noted on bills, receipts and patient records. We believe that the use of trade names is not inherently deceptive, and we are aware of no evidence of abusive or deceptive use of trade names by dentists in Virginia. The use of deceptive trade names in advertising would, of course, already be prohibited under § 54-187 (7) of the Virginia Code and proposed rule 4.4.F. For these reasons, we again urge the Board to actively seek the repeal or modification of § 54-184.

Commercial Practice Restrictions

Virginia Code §§ 54-146, 54-183 and 54-147.1 prohibit employment and other business relationships between dentists and non-dentists, and ban dentists from leasing space from any commercial establishments. As we discussed in our earlier comments, the available empirical evidence indicates that restraints such as these may harm consumers by increasing prices without providing any quality-related benefits. Such restrictions may actually decrease the quality of dental care in the market by decreasing the frequency with which consumers obtain care. Evidence from the optometric area indicates that consumers tend to purchase eyecare less frequently and may even forego care altogether as a result of the higher prices associated with restrictions on commercial forms of practice.[8]

For these reasons, we continue to urge the Board to recommend the modification or repeal of these statutory provisions.

Prepaid Dental Plan Restraints

As discussed in our earlier comments, we believe that several statutory provisions regulating prepaid dental plans will reduce competition in the dental services market and will tend to raise prices without providing any countervailing benefits to consumers. The Board has not proposed changes to these statutory provisions. We therefore again urge the Board to seek the removal of §§ 38.1-903, 904 and 909, and § 38-2-898 because they restrict the development and operation of prepaid dental plans.

Supervision of Dental Hygienists

Section 5.2 of the Board's proposed final regulations requires that the dentist "shall be present and evaluate the patient during the time the patient is in the facility" whenever dental hygienist services are performed. This provision defines the general requirement in § 5.2 that hygienists shall perform their duties under the "direction and control" of an employing dentist or dentist-in-charge. "Direction" is also defined by the Board in § 1.1 of the proposed rules to mean the "presence of the dentist for the evaluation, observation, advice and control over the performance of dental services."

We are concerned that these provisions, which appear to require dentists' "direct" supervision of dental hygienists in all instances, may unnecessarily restrict the efficient delivery of high quality preventive dental services, and thereby reduce consumers' access to those services. We ask the Board to consider whether a more relaxed supervision standard for all or certain service settings would adequately protect the public while allowing dentists the flexibility to determine whether a higher level of supervision is appropriate in particular circumstances. We do not attempt to offer advice on the quality of care or medical safety questions that may be involved in determining the appropriate supervision standard, but we are unaware of any evidence indicating that a less restrictive standard than that proposed by the board, such as general supervision, does not adequately protect the public's health and safety.

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[8] Public Health Service, Eyeglasses and Contact Lenses: Purchases, Expenditures, and Sources of Payment, National Health Care Expenditures Study 4 (1979); Benham and Benham, Regulating through the Professions: A Perspective on Information Control, 18 J.L. & Econ. 421, 438 (1975); Kernan, U.S. Health Profile, Washington Post, Apr. 26, 1979, at p. C-1, col. 4. Like the empirical studies in the optometric area discussed in detail in our earlier comments, this evidence may be applicable to analogous restrictions in other areas, such as dentistry.

The Legislature just last year amended § 54-200.7 of the Virginia Code to give licensed dental hygienists the right to practice "under the direction" of a supervising dentist. In so doing, the Legislature specifically removed the more stringent requirement that hygienists practice under a dentists' "direct supervision." This action appears to reflect the Legislature's determination that "direct" supervision, which, like the Board's proposed rule § 5.2, requires the physical presence of the dentist, is not necessary in all instances to protect the public.

We understand that most states take a similar position, requiring only that hygienists practice under the dentist's "supervision" or "direction" with no further definition. We further understand that these undefined provisions have been interpreted, in a majority of the states, to mean that hygienists may practice in private offices under a dentist's "general" supervision. General supervision, as you are aware, means that the dentist must in some manner delegate and be responsible for the task, but need not be present in the operatory or office during the hygienist's performance of the service. General supervision has also apparently become the norm in two-thirds of the states for hygienists practicing in non-traditional settings such as schools, state and local public health department clinics, health maintenance organizations, hospitals, and other institutions where dental services are provided. The District of Columbia, for example, permits hygienists to perform their traditional functions (preliminary examination, prophylaxis, polishing of teeth, charting of cavities, applying flourides and other medicinal agents, taking dental x-rays, and oral health care education) under general supervision in all dental service settings.[9] Some states permit this more relaxed standard for practice in institutional settings even though they require direct supervision in private offices. Maryland, for example, permits a waiver of its "on premises" supervision requirements on a facility-by-facility basis for government-owned and operated facilities upon application and good cause shown.[10]

The potential benefits to consumers under a general supervision standard could be substantial. Under it, dentists who need not be present in the operatory or facility during the performance of authorized hygienist services could spend that time engaged in the more complex services for which they were primarily trained, such as diagnosis and treatment of other patients. At the same time, the cost of providing preventive dental care, such as prophylaxis, could be reduced significantly because of the reduced amount of dentist time required to provide those services. Lower costs could, in turn, lead to increased output of dental services, better consumer access to those services, and improved dental health.[11]

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[9] D.C. Code Ann. § 2-3301.2(4)(B) (1985).

[10] Md. Health Occ. Code Ann. § 4-308(d)(2)(1986).

For these reasons, we urge the Board to consider the potential benefits to consumers of adopting a general supervision standard for some or all service settings, or of permitting dentists to exercise their professional judgment in determining the appropriate level of supervision by adopting no standard beyond the "under the direction" requirement enacted by the Legislature.

Conclusion

In sum, we urge the Board to consider the consumer harm that may come from restrictions on truthful, nondeceptive advertising, on commercial forms of practice, and on prepaid dental plans. Such restrictions tend to raise prices and decrease the quality of care. We therefore urge the Board to amend, eliminate or recommend the repeal of the rules and statutory provisions discussed above. We further recommend that the Board consider relaxing the proposed requirement for supervision of dental hygienists.

Sincerely,

William C. MacLeod
Director

Enclosures

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[11] See supra text accompanying notes 3-6.

J-008140

FEDERAL TRADE COMMISSION
Chicago Regional Office

Suite 1437
55 East Monroe Street
Chicago, Illinois 60603
Area Code 312 353-8156

May 13, 1987

The Honorable Harry Hill
State Representative
State Capitol
Jefferson City, MO 65101

Dear Mr. Hill:

The Federal Trade Commission staff is pleased to have this opportunity to respond to your letter of March 3, 1987, requesting our comments on House Bill 529 and Senate Bill 232.[1] These bills would restrict advertising by dentists. We recognize and support Missouri's interest in preventing deceptive advertising practices by dentists, but we believe that HB 529 and SB 232 would adversely affect consumer welfare by limiting the dissemination of truthful, non-deceptive information about Missouri dentists and their services. We therefore recommend that neither of these bills be enacted. For similar reasons, we also urge Missouri to reconsider its existing statutory provisions that restrict dentists in advertising their areas of specialization.

I. INTEREST AND EXPERIENCE OF THE FEDERAL TRADE COMMISSION

Our interest in this legislation stems from the Commission's mandate to enforce the antitrust and consumer protection laws of the United States. Section 5 of the FTC Act prohibits unfair methods of competition, and unfair or deceptive acts or practices. In enforcing this statute, the Commission staff has gained substantial experience in analyzing the impact of various restraints on competition and the costs and benefits to consumers of such restraints.

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[1] The views presented in this letter are those of the Chicago Regional Office and Bureaus of Competition, Consumer Protection, and Economics and are not necessarily those of the Commission itself. The Commission has, however, voted to authorize the staff to present these comments.

For several years, the Commission has been investigating the effects of public and private restrictions on the business practices of dentists, optometrists, lawyers, physicians, and other state-licensed professionals. Over the past few years, the Commission staff has submitted numerous written comments to state boards of dentistry analyzing the effects on consumer welfare of various regulations governing advertising and other practices.[2] In addition, as part of the Commission's efforts to foster competition among licensed professionals more generally, we have examined the effects of public and private restrictions that limit the ability of professionals to engage in nondeceptive advertising.[3] Studies in other professional areas suggest that prices for professional goods and services are lower where advertising exists than where it is restricted or prohibited.[4] Although some concern has been voiced that advertising may lead to lower quality services, the empirical evidence suggests that the quality of services provided by firms that advertise is at least as high as, if not higher than, that of firms that do not advertise.[5] Therefore, to the extent that truthful and nondeceptive advertising is restricted, higher prices and a decrease in consumer welfare are likely to result. For this reason, we believe that only false or deceptive advertising should be prohibited. Any other standard is likely to suppress the dissemination of potentially useful information and may contribute to an increase in prices.

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[2] See, e.g., Letter to Ms. Nancy T. Feldman, Executive Director, Virginia State Board of Dentistry (April 23, 1987); Letter to Mr. R.B. Thompson, Executive Director, Kentucky Board of Dentistry (Nov. 21, 1986); Letter to Ms. Nancy T. Feldman, Executive Director, Virginia State Board of Dentistry (April 2, 1986); Letter to Mr. H. Fred Varn, Executive Director, Florida Board of Dentistry (Nov. 6, 1985); Letter to Mr. Dale J. Forseth, Executive Secretary, Minnesota Board of Dentistry (Sept. 23, 1985); Letter to Mr. Robert J. Siconolfi, Executive Secretary, New Jersey State Board of Dentistry (March 19, 1985).

[3] *See, e.g.*, In re American Medical Associaton, 94 F.T.C. 701 (1979), *aff'd*, 638 F.2d 443 (2d Cir. 1980), *aff'd mem. by an equally divided Court*, 455 U.S. 676 (1982). The thrust of the *AMA* decision -- "that broad bans on advertising and soliciting are inconsistent with the nation's public policy" (94 F.T.C. at 1011) -- is consistent with the reasoning of recent Supreme Court decisions involving professional regulations. *See, e.g.*, Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626 (1985) (holding that an attorney may not be disciplined for soliciting legal business through printed advertising containing truthful and nondeceptive information and advice regarding the legal rights of potential clients or for using nondeceptive illustrations or pictures); Bates v. State Bar of Arizona, 433 U.S. 350 (1977) (holding a state supreme court prohibition on advertising invalid under the First Amendment and according great importance to the role of advertising in the efficient functioning of the market for professional services); and Virginia State Board of Pharmacy v. Virginia Citizens Council, 425 U.S. 748 (1976) (holding a Virginia prohibition on advertising by pharmacists invalid).

II. ANALYSIS OF ADVERTISING RESTRAINTS CONTAINED IN HB 529 AND SB 232

A. Current Law

Missouri law currently prohibits a general dentist from stating that he or she is a "specialist" or from using the phrase "limited to the specialty of" unless the dentist holds a Missouri specialist certificate and license.[6] Those dentists who do not meet these criteria are further prohibited from using terms denoting state-recognized specialties in their advertisements unless they also state that they are not licensed in Missouri as specialists.[7] In addition, Missouri dentists may not advertise any terms denoting or implying any specialty areas which are not recognized by the American Dental Association ("ADA").[8] These provisions impose extensive restrictions on dentists who wish to advertise one or more specific areas of dentistry. In light of the analysis that follows, we recommend that Missouri consider whether less restrictive provisions might adequately protect consumers.[9]

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[4] Cleveland Regional Office and Bureau of Economics, Federal Trade Commission, Improving Consumer Access to Legal Services: The Case for Removing Restrictions on Truthful Advertising (1984); Bureau of Economics, Federal Trade Commission, Effects of Restrictions on Advertising and Commercial Practice on the Professions: The Case of Optometry (1980); Benham and Benham, Regulating Through the Professions: A Perspective on Information Control, 18 J.L. & Econ. 421 (1975); Benham, The Effects of Advertising on the Price of Eyeglasses, 15 J.L. & Econ. 337 (1972).

[5] Bureau of Economics, Federal Trade Commission, Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry (1980); Muris and McChesney, Advertising and the Price and Quality of Legal Services: The Case for Legal Clinics, 1979 Am. B. Found. Research J. 179 (1979). See also, Cady, Restricted Advertising and Competition: The Case of Retail Drugs (1976); McChesney and Muris, The Effects of Advertising on the Quality of Legal Services, 65 A.B.A.J. 1503 (1979).

[6] Mo. Rev. Stat. § 332.321(2)(14)(e)(1984).

We believe it is important that a dentist with expertise or experience in specific areas be allowed to communicate that expertise to the public. In our view, only specialization claims that are deceptive, such as a claim that falsely states or implies that a dentist is a specialist, need be prohibited. Dentists should be free to make truthful, nondeceptive claims that they concentrate in a particular field of dentistry, that their practice is limited to a particular area, or to otherwise truthfully advertise their expertise in a particular area of dentistry regardless of whether they have a specialist certificate and license.

B. Proposed section 332.321(2)(14)(e) would significantly expand the current restraints

Under HB 529 and SB 232, false, misleading or deceptive advertisements or solicitations would include, but not be limited to:

> [a]ny announcement in any form including the terms "specialist" or "specializing in", or the phrases "limited to ~~the specialty of~~" or "practice limited to", or other like or similar terms or phrases unless each person named in conjunction with the term or phrase, or responsible for the announcement, holds a

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[7] Id. at § 332.321(2)(14)(f). Section 332.321(2)(14)(f) of Missouri's current law is Section 332.321(2)(14)(g) of HB 529 and SB 232.

[8] Id. at § 332.321(2)(14)(g). This section would become § 332.321(2)(14)(i) in HB 529 and SB 232.

[9] In this letter, we are not commenting upon the general merits of states' certifying professionals as specialists.

> valid Missouri certificate and license evidencing that he is a specialist in that area.[10]

The bills would prohibit a dentist from truthfully advertising that his or her practice is "limited to" a particular area of dentistry unless he or she holds a valid Missouri dentistry specialist certificate and license. The State of Missouri licenses every dentist to practice in all branches of dentistry.[11] Since Missouri also allows dentists to limit their practice to particular areas of dentistry, these dentists should be able to truthfully advertise that their practice is, for example, "limited to children's dentistry" or to "cosmetic dentistry" without having to be certified and licensed as a Missouri dental specialist. Dentists may acquire expertise through education, training, or practice in a particular field even though such development does not lead to certification. By prohibiting dentists from truthfully advertising their areas of concentration, Missouri would be depriving consumers of useful information that allows them to compare the quality and price of services provided by all legally qualified practitioners -- general dentists as well as specialists.

There is no reason to believe that consumers will be misled by the phrase "practice limited to." While this phrase may be a term of art among dentists denoting formal certification as a specialist, we are not aware of any evidence indicating that such a phrase means anything more to a consumer than that a dentist has limited his or her practice to a particular area of dentistry.

In addition to prohibiting the use of the phrase "practice limited to," proposed section 332.321(2)(14)(e) would also expand current law to prohibit dentists from using "other like or similar terms or phrases" in describing their practice unless they hold a valid Missouri specialist certificate. This provision is troublesome because it is unclear what exactly "other like or similar terms or phrases" might be held to include. For example, would a dentist not certified as a specialist be able to state that he or she has "twenty years of experience" in a particular field of dentistry? Since the proposed law is unclear, it is likely that some dentists will refrain from advertising out of fear of crossing the vague line of illegality. This provision would further limit the truthful, nondeceptive information that is available to consumers.

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[10] This section, and the sections cited hereinafter, are from HB 529. The language in SB 232 is virtually identical. The underlined language is the new language proposed by the two bills that is to amend current Missouri law.

[11] Mo. Rev. Stat. § 332.050(2)(1984).

We are aware that the Missouri Supreme Court recently found the state's present law on specialist advertising to be consistent with the First Amendment.[12] HB 529 and SB 232, however, would appear to result in a significant further narrowing of dentists' commercial speech. Thus, the proposed sections might or might not pass constitutional muster. Yet even if the advertising restrictions contained in these bills were found to be compatible with the First Amendment, we still believe that Missouri consumers would be better served by more narrowly tailored advertising restrictions.

C. Proposed section 332.321(2)(14)(f) would appear to prohibit the same advertising practices as previously described proposed section 332.321(2)(14)(e)

Under HB 529 and SB 232, false, misleading or deceptive advertisements or solicitations would include, but not be limited to:

> [a]ny announcement in any form including the terms "specialist", or "specializing in" or the phrases "limited to the specialty of" or "practice limited to", or other like or similar terms or phrases unless the area of practice so referred to is a specialty area recognized by the American Dental Association.

We question the need for HB 529 and SB 232's proposed section 332.321(2)(14)(f). Proposed section 332.321(2)(14)(e) would forbid the use of the terms "specializing in," "limited to," or other "like or similar terms or phrases" unless a dentist is a certified specialist under Missouri law. Since Missouri only certifies dentists in the specialty areas approved by the American Dental Association for specialty practice, it appears that proposed section 332.321(2)(14)(f) would prohibit the same advertising practices as proposed section 332.321(2)(14)(e).

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[12] Parmley v. Missouri Dental Board, 719 S.W.2d 745 (1986)(en banc).

Thus, our previous analysis of proposed section 332.321(2)(14)(e) is also applicable to proposed section 332.321(2)(14)(f).

III. ANALYSIS OF MANDATORY DISCLOSURES CONTAINED IN HB 529 AND SB 232

A. Overview

As a general matter, we believe that mandatory disclosures often deter advertising. HB 529 and SB 232 impose several new disclosure requirements that appear burdensome, overlapping, and to some degree confusing.

B. Proposed section 332.321(2)(14)(h) is unclear and may confuse consumers

Under HB 529 and SB 232, false, misleading or deceptive advertisements or solicitations would include, but not be limited to:

> [a]ny announcement of services by a general practitioner which does not state in a prominent manner that the dental practice is one of general dentistry. Said announcement of the general practice of dentistry must be at least as prominent as the announcement of services offered.

The meaning of proposed section 332.321(2)(14)(h) is unclear. Would dentists not certified as specialists merely be required to state prominently that they are general dentists, or would they be required to state that their actual practice is one of general dentistry? If the latter interpretation is the one that ultimately prevails, then a Missouri dentist who wishes to advertise and provide only a particular dental service would be forced to advertise that he or she provides and is interested in providing general dental services. Indeed, this provision could ultimately provide a disservice to those consumers who respond under the assumption that the general dentist provides a full range of dental services when in fact the dentist is willing to provide only certain dental services.

The various disclosure provisions contained in HB 529 and SB 232, when read in conjunction with the rest of the existing regulations governing Missouri general dentists, appear to be overlapping and quite burdensome. For example, if either HB 529 or SB 232 was passed, a general dentist would be required in certain situations to place two disclosures within one single advertisement. Section 332.321(2)(14)(f) of Missouri's current law[13] requires a dentist who wishes to advertise using a term denoting a recognized specialty such as orthodontics to state: "Notice: the following dentist(s) in this practice is (are) not licensed in Missouri as specialists [sic] in the advertised dental specialty(s) of . . . ." Since particular services would have been announced, proposed section 332.321(2)(14)(h) would further require a dentist to state that his or her dental practice is one of general dentistry[14] even if it is not.

C. Proposed section 332.321(2)(14)(i) would allow certain advertising but require an unnecessary disclaimer

Under HB 529 and SB 232, false, misleading or deceptive advertisements or solicitations would include, but not be limited to:

> [a]ny announcement containing any terms [denoting or] implying specialty areas which are not recognized by the American Dental Association unless the announcement contains a disclaimer as prescribed by rule of the board.

Proposed section 332.321(2)(14)(i) would permit terms to be used that imply specialty areas that are not recognized by the American Dental Association if such terms are accompanied by a disclaimer that would be prescribed by rule of the Missouri Dental Board. To the extent that the bill would relax current restrictions and allow dentists to use terms in their advertisements that imply specialty areas which are not recognized by the ADA, the bills seem to improve upon current law. However, under these circumstances, we have strong reservations about the desirability for a disclaimer. As previously discussed, we are unaware of any evidence indicating that consumers are misled when particular dental services, regardless of whether recognized by the ADA or not, are truthfully advertised. Since a disclaimer inevitably places costs and burdens on advertising, it appears likely that any disclaimer that the Board prescribes will have the effect of deterring some truthful and nondeceptive advertising.[15]

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[13] Section 332.321(2)(14)(f) of Missouri's current law is Section 332.321(2)(14)(g) of HB 529 and SB 232.

[14] Proposed sections 332.321(14)(h) and 332.321(14)(i) of HB 529 and SB 232 could also operate together to require two similar disclosures within a single advertisement.

D. Proposed section 332.321(2)(14)(j) would appear to burden advertisements for multi-location dental practices

Under HB 529 and SB 232, false, misleading or deceptive advertisements or solicitations would include, but not be limited to:

> [a]ny announcement that does not name a responsible dentist for the practice being advertised. The dentist shall be currently licensed to practice dentistry in this state and shall be regularly employed in and responsible for the management, supervision and operation of each office location listed in the advertisement.

Proposed section 332.321(2)(14)(j) appears to be much more restrictive than is necessary to protect Missouri's interest in ensuring that a named dentist will be responsible for each individual dental practice. We recognize that Missouri may wish to ensure identification and accountability of individual dentists practicing under a trade name. However, proposed section 332.082 would already require every dentist who is part of a multidentist practice to designate "for each patient a dentist of record for each procedure performed for a patient." This proposed provision would appear to adequately ensure identification and accountability of individual dentists without unduly restricting nondeceptive advertising.

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[15] This provision further appears to be internally inconsistent with proposed sections 332.321(2)(14)(e) and 332.321(2)(14)(f) which more broadly prohibit the use of the terms "specializing in," "limited to," and other "like or similar terms or phrases."

In contrast, proposed section 332.321(2)(14)(j) would broadly prohibit all announcements that do not name a responsible dentist for the practice being advertised. Chain dental offices, for example, would apparently have to state the name of the dentist who is responsible at each of many locations. This requirement could be extremely burdensome, especially in broadcast advertising. It would appear that Missouri could advance its legitimate concerns through less burdensome means, such as by requiring a listing of the dentists to be posted at each location and/or by requiring dentists' names to appear on the patients' records and on all invoices and receipts.

IV. CONCLUSION

We believe that Missouri's legitimate interest in protecting its consumers from misleading dental advertisements is poorly advanced by HB 529 and SB 232. Indeed, these two overly broad bills are likely to harm consumers by limiting truthful and nondeceptive information about the kinds of services that general dentists licensed in Missouri provide in accordance with Missouri law. Provisions such as these that go far beyond prohibiting false and deceptive advertising have the potential to result in a loss of consumer welfare by making it more difficult for consumers to identify the types of dental services that they prefer and by increasing the prices of dental services. For all of the above reasons, the staff of the Federal Trade Commission recommends that these bills not be enacted. We further recommend that Missouri re-examine its existing dental laws and consider whether its existing provisions may unnecessarily deprive consumers of truthful, nondeceptive information about dental services. We appreciate having had this opportunity to provide our views on these issues.

Sincerely,

John M. Peterson

John M. Peterson
Director
Chicago Regional Office

JMP:jd

BUREAU OF COMPETITION

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

May 1, 1987

The Honorable Tim Leslie
California Assembly
State Capitol
Sacramento, California 94249-0001

Dear Mr. Leslie:

We are pleased to respond to your request for our views on Assembly Bill No. 1732, now pending before the Health Committee of the California Assembly.[*] The bill would place certain restrictions on the ability of physicians to dispense prescription drugs to their patients. It would require licensure of dispensing physicians by the Board of Pharmacy and permit physician dispensing only if the dispensing physician's office is located more than 5 miles from a pharmacy, the medication dispensed is no more than a 72-hour supply, and no dispensing fee is charged to the patient. The effect of the bill would be to prohibit physician dispensing in most areas of the state and to eliminate any financial incentive for physicians to dispense in the remainder of the state. We believe that these restrictions are likely to be harmful to consumers.

We do not endorse physician dispensing as preferable to pharmacist dispensing. Rather, we support consumer choice among qualified providers of prescription drugs. Physician dispensing maximizes consumers' options in the purchasing of prescription drugs, and we believe it may increase competition among physicians and between physicians and pharmacists, and lead to lower prices and better services.

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[*] These comments represent the views of the Federal Trade Commission's Bureaus of Competition, Economics, and Consumer Protection, and not necessarily those of the Commission itself. The Commission has, however, voted to authorize the staff to submit to these comments to you. The Commission's staff has been investigating restrictions on competition in the sale of prescription drugs and has examined proposals by some members of the pharmacy profession to have states impose restrictions on physician dispensing.

The dispensing of medication by physicians is a traditional part of medical practice that was once quite common and is currently authorized in all but a very few states. Some consumers may value the option not to have to make a separate trip to a pharmacy to obtain medicine prescribed by their physician. Indeed, the same patient may have different preferences at different times. A parent with a two-year-old child suffering the pain of an ear infection may desire one-stop shopping, whereas the same parent may prefer to get prescription vitamins for the child at a pharmacy. There are increasing numbers of group medical practices and walk-in clinics that are, in response to consumer demand, providing additional options and convenience, and this trend is generating increased competition in the sale of prescription drugs.

California law now allows consumers to choose which provider of pharmaceutical services they prefer and provides safeguards to protect the public health. Under existing law, prescription drugs may be dispensed by physicians only to their own patients; the drugs must be necessary for the treatment of the condition for which the physician is attending the patient; and the drugs may not be furnished to the patient by a nurse or other employee of the physician. Dispensing physicians must also comply with the same labeling, record-keeping, and packaging requirements that are imposed upon pharmacists. Enforcement authority is vested in the Board of Medical Quality Assurance and the Board of Osteopathic Examiners. The existing regulatory scheme appears to be designed to protect public health by ensuring that physicians who dispense meet the health and safety standards applicable to pharmacists, and also to allow patients the benefits of choice among different providers of dispensing services.

Section 1 of the bill sets forth two justifications for the restrictions it would impose. The first is that the pharmacist may prevent the inadvertent misuse of drugs from multiple prescribers and that patient health is placed at risk when the oversight of the pharmacist is circumvented. Pharmacists can provide a check against misuse due to multiple prescribers, provided that patients use only one pharmacist and that the pharmacist maintains complete patient profiles. Even where these conditions are not met, pharmacists may provide other services that are beneficial to consumers, including a review of the prescription for errors, potential drug allergies and interactions, and patient counseling. At the same time, physicians are responsible for their prescribing choices and are, by virtue of their contact with the patient at the time of prescribing and familiarity with the patient's medical history, in an excellent position to consider drug allergies and interactions and provide drug counseling. Moreover, medication errors that occur due to miscommunication between physicians and pharmacists, such as misinterpretations of prescription orders, would be reduced. Finally, as noted above, California law already requires physicians who dispense to meet the same standards applicable to pharmacists with respect to record-keeping, labeling, packaging, and use of support personnel. In these circumstances, the fact that pharmacists do provide some services that have value to consumers does not mean that consumers should be required to buy those services rather than the services offered by physicians.

The second justification offered in support of the bill is, essentially, that physicians who dispense may be led by their own financial interests to harm patients by overprescribing or prescribing inappropriately. This, of course, is the same issue that arises whenever a physician orders any medical procedure he provides himself, including lab work, diagnostic imaging, or even follow-up visits. The potential conflict of interest raised by physician dispensing seems no different from the potential conflict created when any provider of expert services recommends a product or service and then offers to supply it, such as a stockbroker recommending an investment or a mechanic recommending the replacement of brakes on a car. Indeed, pharmacists face this potential conflict when they recommend vitamins or non-prescription drugs.

In general, we believe that the best way to deal with this sort of problem is to encourage competition, not to restrict it by banning an entire category of transactions that consumers may want. Although there is some incentive to sell additional products or services under such circumstances, competition provides some incentive not to do so because a physician who would exploit patients through improper dispensing risks the loss of his reputation for integrity, and thus the loss of his patients to other physicians. Moreover, exploitive practices are already prohibited by more narrowly focused state laws and regulations. Thus, there is the threat of disciplinary proceedings by the Board of Medical Quality Assurance or the Board of Osteopathic Examiners, state enforcement of safety and health regulations, and state enforcement of statutory prohibitions of fraudulent or unfair acts or practices.

Finally, the provision of the bill that would require physicians who wish to dispense to obtain a license from the Board of Pharmacy may exacerbate the risks to competition inherent in professional self-regulation. There may be incentives for pharmacist-regulators to erect barriers to entry or otherwise to limit competition from physicians who wish to dispense. In addition, although the bill retains the current enforcement authority of the Board of Medical Quality Assurance and the Board of Osteopathic Examiners, it is not clear whether the Board of Pharmacy could revoke physicians' licenses to dispense for reasons properly within the province of the medical boards.

In sum, dispensing of prescription drugs by physicians increases consumers' ability to choose among qualified providers of pharmaceutical services. The option not to make a separate trip to a pharmacy may be important to some consumers. The resulting competition among physicians, and between physicians and pharmacists, may produce lower prices and improved services. We believe that consumers should not be deprived of these potential benefits unless real evidence demonstrates that physician dispensing has harmed or is likely to harm public health and safety, and that less restrictive safety and health standards, such as those already imposed by law, are insufficient to protect the public. The burden should be on the proponents of the bill to produce such evidence because the bill would eliminate the benefit of consumer choice. In the absence of such evidence, the changes to existing law proposed in the bill appear likely to serve the economic interests of pharmacists and drug stores and to reduce consumer welfare.

Sincerely yours,

Jeffrey I. Zuckerman
Director
Bureau of Competition

BUREAU OF
CONSUMER PROTECTION

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

April 23, 1987

Ms. Gwen Mathews
Executive Director
Florida Board of Dentistry
130 North Monroe Street
Tallahassee, FL 32399-0705

Dear Ms. Mathews:

The staff of the Federal Trade Commission[1] is pleased to offer these comments in response to your invitation of April 3, 1987, for public comments on the Florida Board of Dentistry's proposed regulations restricting dental advertising.

Advertising is beneficial to consumers because it provides information about the individuals or firms offering services that they may wish to purchase. Information facilitates purchase decisions that reflect true consumer preferences, and promotes the efficient delivery of services. We therefore urge the Board to eliminate the provisions in its proposed rules that restrict the use of truthful, nondeceptive advertising. We also suggest that the Board recommend legislation repealing state laws that similarly restrict such advertising.

Interest and Experience of the Federal Trade Commission

The Federal Trade Commission is empowered under 15 U.S.C. §§ 41 *et seq*. to prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. Pursuant to this statutory mandate, the Commission has attempted to encourage competition among members of licensed professions to the maximum extent compatible with other legitimate state and federal goals. For several years, the Commission staff has been investigating the competitive effects of restrictions on the business practices of state-licensed professionals, including dentists, optometrists, lawyers, physicians, and others. Our goal has been to identify and seek the removal of restrictions that impede competition and increase cost, without providing significant countervailing benefits to consumers.

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[1] These comments represent the views of the Federal Trade Commission's Bureaus of Consumer Protection, Economics, and Competition, and do not necessarily represent the views of the Commission or any individual Commissioner. The Commission, however, has voted to authorize the submission of these comments.

Bicentennial of the United States Constitution
(1787-1987)

As a part of the Commission's efforts to foster competition among licensed professionals, it has examined the effects of public and private restrictions that limit the ability of professionals to engage in nondeceptive advertising.[2] Studies indicate that prices for professional goods and services are lower where advertising exists than where it is restricted or prohibited.[3] Studies also provide evidence that restrictions on advertising raise prices but do not increase the quality of goods and services.[4] Therefore, to the extent that nondeceptive advertising is restricted, higher prices and a decrease in consumer welfare may result.

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[2] See, e.g., American Medical Ass'n, 94 F.T.C. 701 (1979), aff'd, 638 F.2d 443 (2d Cir. 1980), aff'd mem. by an equally divided Court, 455 U.S. 676 (1982). The thrust of the AMA decision -- "that broad bans on advertising and soliciting are inconsistent with nation's public policy" (94 F.T.C. at 1011) -- is consistent with the reasoning of recent Supreme Court decisions involving professional regulations. See, e.g., Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626 (1985) (holding that an attorney may not be disciplined for soliciting legal business through printed advertising containing truthful and nondeceptive information and regarding the legal rights of potential clients to use nondeceptive illustrations or pictures); Bates v. State Bar of Arizona, 433 U.S. 350 (1977) (holding invalid state supreme court prohibition on advertising under the First Amendment and according great importance to the role of advertising in the efficient functioning of the market for professional services); Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976) (holding invalid a Virginia prohibition on advertising by pharmacists).

[3] Cleveland Regional Office and Bureau of Economics, Federal Trade Commission, Improving Consumer Access to Legal Services: The Case for Removing Restrictions on Truthful Advertising (1984); Bureau of Economics, Federal Trade Commission, Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry (1980); Benham and Benham, Regulation Through the Professions: A Perspective on Information Control, 18 J.L. & Econ. 421 (1975); Benham, The Effects of Advertising on the Price of Eyeglasses, 15 J.L. & Econ. 337 (1972).

[4] Bureau of Economics, Federal Trade Commission, Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry (1980); Muris and McChesney, Advertising and the Price and Quality of Legal Services: The Case for Legal Clinics, 1979 Am. B. Found. Research J. 179 (1979). See also Cady, Restricted Advertising and Competition: The Case of Retail Drugs (1976).

We have examined various justifications that have been offered for restrictions on advertising and have concluded that these arguments do not warrant restrictions on truthful, nondeceptive communications. For this reason, we believe that only false or deceptive advertising should be prohibited. Any other standard is likely to suppress the dissemination of potentially useful information and contribute to an increase in prices.

Affirmative Disclosure Obligations

Any disclosure obligation increases advertising costs, either because it increases the length of the message or requires practitioners to forego some portion of the advertising message they would have delivered had the space not been occupied by the disclosure. Unnecessary disclosure requirements could therefore result in less useful information being made available to consumers. Consequently, we believe that disclosures should be mandated only where they are necessary to prevent deception. Although affirmative disclosures may be justified in some instances, several of the Board's proposed regulations appear broader than necessary to prevent deception of the public.

Rule 21G-4.002(2) would require that all advertising "contain the name, address, telephone number of the dentist, and of other dentists with whom the dentist is associated."[5] This rule could impose burdensome advertising costs on those group practices that include many partners or associates, and could make any advertising by such firms impractical, particularly broadcast advertising. We believe that the Board can better accomplish the goal of ensuring identification and accountability of individual practitioners by requiring that the name of each dentist be displayed in a conspicuous place, or noted on bills, receipts and patient records.

Rule 21G-4.002(4) would require that dental advertisements mentioning a fee include "a description of [the] service using the exact wording for that service contained in the American Dental Association 'Code on Dental Procedures and Nomenclature.'" This requirement is troublesome for two reasons. First, it appears to require advertisers to use technical terminology that may be confusing and not easily understood by consumers. It thus limits the ability of dental advertisers to convey their message as effectively as possible and may have a chilling effect upon desirable advertising. Second, this provision appears to preclude the advertising of fees for any services that are not included in the ADA Code on Dental Procedures and Nomenclature, such as new or innovative techniques that are not yet widely used by dental practitioners.

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[5] We note that this language was previously included in the statute but was specifically deleted in amendments adopted by the legislature last year.

Section 21G-4.002(3)(g) provides that advertisements for free or discounted services must comply with Section 455.25 of the Florida Statutes. This statutory provision requires various health care providers, including dentists, to include a lengthy disclosure in all advertisements for free or discounted services.[6] According to this disclosure, consumers are not obligated to pay for any treatment performed as a result of responding to an ad for free or discounted services. This disclosure requirement is not necessary to prevent deception since there is nothing inherently misleading in offering free or discounted services. Furthermore, the disclosure may be so burdensome as to reduce the amount of price advertising. Not only will advertising costs increase, but the dentist's ability to provide necessary dental services to his or her patients may be impaired. According to this provision, if a consumer responds to an ad for a discount on dental x-rays, and the x-rays reveal that the consumer has an abscess that needs immediate treatment, the consumer could have this work done and then legally refuse to pay for it. Such a result would most likely reduce dentists' incentive to advertise free or discounted services, or else encourage dentists to avoid the application of this provision by delaying necessary treatment for several days. The Board can better accomplish its apparent goal of preventing dentists from charging consumers for hidden costs by requiring that dentists seek the patient's permission before undertaking any additional procedure that is not included in treatment advertised as free or discounted.

We recognize that, in general, the more information that is available to consumers, the better prepared they will be to make well-reasoned purchases. We believe, however, that the disclosures required by the Board are counterproductive. By increasing advertising costs, they may discourage some dentists from advertising and thereby deny consumers useful information respecting available dental services.[7] We recommend that the Board not adopt these provisions, and that it seek the repeal of the underlying statutory provision, Fla. Stat. § 455.25.

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[6] The required disclosure consists of the following:

> The patient and any other person responsible for payment has a right to refuse to pay, cancel payment, or be reimbursed for payment for any other service, examination, or treatment which is performed as a result of and within 72 hours of responding to the advertisement for free, discounted fee, or reduced fee service, examination, or treatment.

[7] The Board should bear in mind that elimination of these requirements would not preclude consumers who desire such information from requesting it from the advertiser.

Prohibitions on Solicitation

Rule 21G-4.002(7) would prohibit all "in person and telephone solicitation of dental services by a dentist or his agent." This provision would restrict the flow of commercial information more than is necessary to protect consumers because it would preclude truthful, nondeceptive communications in circumstances that pose little or no risk of undue influence.

In-person and telephone contacts may provide consumers with truthful, nondeceptive information that will help them select a dentist. Such contacts can convey information about the availability and terms of a dentist's services and, in this respect, they serve much the same function as print advertising. See Ohralik v. Ohio State Bar Association, 436 U.S. 447, 457 (1978).

Some restrictions on solicitation may be justified. Certainly, false or deceptive solicitation and solicitation of persons who have informed the dentist that they do not wish to be contacted by him may appropriately be prohibited. We recognize that in certain circumstances in-person and telephone solicitation could result in overreaching or undue influence, and a state may therefore legitimately insist that dentists and their agents not exert such undue influence. See Ohralik v. Ohio State Bar Association, 436 U.S. 447 (1978). But in our view, this does not justify a blanket ban on the use of all in-person and telephone solicitation. Such as ban might, for example, bar dentists from speaking to interested groups about dental care, a situation unlikely to result in overreaching or undue influence.

The Federal Trade Commission considered the concerns that underlie the Ohralik opinion when it decided American Medical Association, 94 F.T.C. 701 (1979). After weighing the possible harms and benefits to consumers, the Commission ordered the AMA to cease and desist from restricting solicitation, but permitted the AMA to proscribe uninvited, in-person solicitation of persons who, because of their particular circumstances, ~~may be~~ vulnerable to undue influence. We suggest the Board consider using this standard, which protects consumers from harm while allowing them to receive information about available dental goods and services.

Telephone solicitation, like in-person solicitation, can also convey useful information to consumers, and it may present no greater risk of the exercise of undue influence than does in-person solicitation. Consumers are accustomed to telephone marketing. They receive calls from persons offering the sale of various goods and services, conducting surveys about the products and services consumers use, seeking contributions to charities, and requesting support for political candidates. Consumers can easily terminate offers of dental services communicated by telephone.

Although the standard for in-person solicitation discussed above may also be appropriate here, we are not prepared to make a final recommendation on the proper treatment of telephone solicitation. We do believe, however, that it should not be regulated any more stringently than in-person solicitation, and that an absolute ban on telephone solicitation is unnecessarily restrictive.

Prohibitions on Quality and Specialization Claims

Section 21G-4.002(3)(c) and Fla. Stat. § 466.019(2)(c) prohibit advertisements containing "laudatory statements about the dentist or group of dentists." In addition, Section 21G-4.002(3)(e) of the Board's proposed Rules and Fla. Stat. § 466.019(2)(e) prohibit any dental advertisement which "relates to the quality of dental services as compared to other available dental services." We recommend that the Board eliminate these proposed rules and seek the repeal of the statutory provisions.

These two provisions in effect prohibit virtually all quality and superiority claims. These prohibitions restrict many forms of comparative advertising, which can be a highly effective means of informing and attracting customers. They also lessen competition among dentists. When sellers cannot truthfully compare the attributes of their services to those of their competitors, their incentive to improve or offer different products, services, or prices is likely to decrease.

Bans on laudatory claims are particularly likely to injure competition and consumers when they are interpreted to prohibit a wide range of factual statements. For example, virtually all statements about a practitioner's qualifications, experience, or performance can be considered to be laudatory. Bans on all such claims would make it very difficult for dentists to provide consumers with truthful information about the differences between their services and those of their competitors.

Section 21G-4.002(5) of the proposed rules allows general dentists to advertise specialty services so long as the advertisement states that the service will be performed by a general dentist. Because we believe it is important that general dentists with expertise or experience in specific areas be allowed to communicate that expertise or experience to the public, we support the Board's effort to allow general dentists to advertise specialty services. In our view, only specialization claims that are deceptive, such as a claim falsely stating that a dentist is a specialist, need be prohibited. The Board's proposed rule apparently leaves general dentists free to make truthful, nondeceptive claims that they concentrate in a particular field of dentistry, if accompanied by a disclosure that they are general dentists. Although we are not convinced that this affirmative disclosure requirement is necessary to avoid deception, it may not be greatly burdensome and it apparently permits dentists to promote the whole range of services they are licensed to perform.

Prohibitions on Appeals to Fear

Section 21G-4.002(3)(f) of the proposed rules and Fla. Stat. § 466.019(2)(f) prohibit any dental advertising which "is likely to appeal primarily to a layperson's fears." We urge the Board to eliminate this Rule and seek the repeal of the statutory provision.

This particular restriction is ambiguous in that it could be intended to ban ads intended to heighten fears or it could be intended to prohibit ads intended to diminish fears. Under either interpretation, however, the restriction is overly broad and susceptible to subjective interpretations that may have little to do with the truth or falsity of a particular statement.

If the purpose of the provision is to prevent ads intended to heighten consumer fears, this purpose could best be met through the Board's prohibition on deceptive or misleading ads under Section 21G-4.002(3). If the Board construes this provision as prohibiting all ads intended to diminish consumer fears, then this provision could deter dentists from engaging in advertising that dentists think the Board would consider likely to allay a layperson's fears, but which is, nevertheless, nondeceptive and beneficial to consumers. In fact, millions of Americans are dental phobics -- "so terrified of dental treatment that they avoid it entirely," and millions of other Americans suffer from dental anxiety.[8] Yet "modern dental techniques and equipment have greatly reduced and often eliminated any pain associated with dental treatments."[9] Bans on ads likely to appeal to a layperson's fears could prevent dentists from any advertising directed to those consumers who may be most in need of dental care -- consumers who are so frightened or anxious about dental treatment that they postpone necessary care to the detriment of their dental health. Such bans may even discourage dentists from using such unobjectionable terms such as "gentle" care.

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[8] American Dental Association, Guide to Dental Health 37 (1986).

[9] Id.

Conclusion

In sum, we recommend that the Board not adopt restraints on nondeceptive advertising and that it seek repeal of the statutory provisions discussed above. We believe those changes will provide substantial benefits to the public, and permit access to a wider range of truthful information about the availability of dental services. They should also help to stimulate valuable competition among dentists and improve the efficiency with which dental services are delivered, while still protecting the public from false or deceptive advertising.

Sincerely,

William MacLeod

William MacLeod
Director

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March 31, 1987

Robert G. Esdale
Clerk of the Supreme Court
P. O. Box 157
Montgomery, Alabama 36101

Dear Mr. Esdale:

The Federal Trade Commission staff is pleased to submit these comments concerning proposed amendments to the Code of Professional Responsibility of the Alabama State Bar.[1] Proposed Rules 2-101(D) and 2-112 would restrict lawyers in advertising the fact that they hold a certificate from a professional certifying organization, even if advertising the certification would provide truthful, nondeceptive information to consumers. We believe that such information is generally helpful to consumers in making purchase decisions, and we therefore urge the Court to eliminate those restrictions.

The Federal Trade Commission seeks to promote competition among members of licensed professions to the maximum extent compatible with other legitimate state and federal goals. For several years, the Commission has been investigating the effects of restrictions on the business practices of professionals, including lawyers, optometrists, dentists, physicians, funeral directors, and others. Our goal is to identify and seek removal of restrictions that impede competition, increase costs, and harm consumers without providing countervailing benefits.

The Clerk of the Court indicated that we may also submit comments on other Code provisions with respect to which we could give a useful perspective. We therefore recommend that the Court:

> (1) modify the definition of false and misleading communications in Temporary DR 2-101 (B) and (C) to avoid prohibiting truthful, nondeceptive testimonials, endorsements, statements about a lawyer's experience, and comparisons of particular lawyers and their services;

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[1] This letter represents the views of the FTC's Atlanta Regional Office and the Bureaus of Competition, Consumer Protection, and Economics, and not necessarily those of the Commission. The Commission has, however, voted to authorize the staff to submit these comments to you.

(2) modify Temporary DR 2-102(A) to eliminate the list of approved "public media" that lawyers may use to advertise;

(3) delete the requirement in Temporary DR 2-102(E) that every communication contain a disclaimer as to quality or expertise;

(4) modify Temporary DR 2-103 to eliminate (a) the broad ban on telephone solicitation except for false and deceptive solicitation and solicitation of persons who have expressed their wish not to be contacted and (b) the restrictions on in person solicitation except for false and deceptive solicitation and solicitation of persons who, because of their particular circumstances, are vulnerable to undue influence or who have expressed their wish not to be contacted;

(5) modify Temporary DR 2-104 to avoid prohibiting truthful, nondeceptive statements about a lawyer's specialty; and

(6) delete Temporary DR 3-102(A) and 3-103(A) and (C)(2) to avoid preventing lawyers from establishing multi-disciplinary practices with other professionals.

I. Temporary DR 2-101(D) and 2-112: Advertising of Certification

Temporary DR 2-101(D) and 2-112(a) prohibit any communication by a lawyer stating that he is certified by an organization unless the General Counsel of the Alabama State Bar has approved advertising of that organization's certification program. Such approval will not be granted under DR 2-112(b) unless the General Counsel finds that the advertising of certification "will provide meaningful information that is not false, misleading, or deceptive, for use of the public in selecting or retaining a lawyer."[2]

We agree that advertising should not be false, misleading, or deceptive. Clearly, it would be deceptive for an attorney to advertise that he or she is "certified" in an area of law if no certification procedure exists or if the attorney has not obtained certification, but conduct of that sort is already prohibited by the general rule against deceptive advertising. A lawyer, however, should be able to advertise, without prior approval by the state, any truthful, nondeceptive information about any certification that he or she has obtained, regardless of what organization has issued the certificate. The advertising of certification programs can beneficially provide consumers with facts about attorneys' special skills when certification requirements are reasonably related to assuring proficiency in the subject area certified. On the other hand, when certified attorneys are prohibited from truthfully advertising their training and skills, consumers will be deprived of information to help them choose among qualified practitioners who are certified but who cannot advertise such certification. Moreover, consumers could be led to believe erroneously that attorneys are incompetent to handle their legal needs in a particular field. The potential consumer misunderstanding engendered by this rule could lessen competition in fields for which a certificate is available, by reducing the number of practitioners that the public will patronize, and could thereby raise legal services costs in those subject areas.

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[2] Temporary DR 2-112(b) and (c) provide the procedures for approval for advertising of certification. The language of (b) and (c), however, discusses the "approval of certifying organizations." Such language could be interpreted to require the approval of the establishment or existence of certifying organizations. We assume that this interpretation is not intended.

Temporary DR 2-112 places a restraint on the development of private certifying organizations. Such restraint may also discourage attorneys from taking any training offered by those organizations whose certification programs have not been approved for advertising by the State Bar. The inefficiency and injury to competition would be particularly acute where the requirement of Bar approval for purposes of advertising is not reasonably related to attaining proficiency in the specialized field.[3]

Further, the standard for approval in DR2-112(b), based on whether the advertising of certification provides "meaningful information . . . for use of the public in selecting or retaining a lawyer," is unnecessarily vague. Such a standard requires the General Counsel to determine what kinds of information the public as a whole will find "meaningful" when, in fact, individual consumers may place different values on different kinds of information.

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[3] Use of certificates that are not bona fide, or that are issued by programs not related to improving skills in a subject area, would be prohibited under the rule against "false and misleading" advertising.

We therefore recommend that the Court eliminate the restrictions in DR 2-101(D) and 2-112 so that lawyers who have taken training programs culminating in receipt of a certificate be allowed to communicate that fact. We also recommend that the Court delete the provision for Bar approval of the advertising of certification programs.

II. Communications Concerning a Lawyer's Services

The beneficial effects of advertising are widely recognized. Truthful, nondeceptive advertising communicates information about individuals or firms offering the services that consumers may wish to purchase. Such information helps consumers make purchase decisions that reflect their true preferences and promotes the efficient delivery of services. Before advertising by attorneys was permitted, many Americans failed to obtain the services of an attorney, even when they had serious legal problems.[4] A recent empirical study suggests that the removal of restrictions on the dissemination of truthful information about lawyers and legal services will tend to enhance competition and to lower prices, thereby improving consumer access to the legal system.[5] Although some have voiced concern that advertising may lead to lower quality legal services, the empirical evidence suggests that the quality of legal services provided by firms that advertise is at least as high as, if not higher than, that provided by firms that do not advertise.[6]

False and deceptive advertising, however, can have significant negative effects on both competition and consumer welfare. Therefore, we fully endorse the view that such advertising should be prohibited. We are concerned, however, that Temporary DR 2-101(B) and 2-101(C) may impede the flow of truthful information to consumers without providing any countervailing benefits. Subsection 2-101(B) prohibits communication that:

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[4] For example, a nation-wide survey in 1974 by the American Bar Foundation and the American Bar Association found that only 9 percent of the people who had a property damage problem, 10 percent of those with landlord problems, and 1 percent of those who felt that they were the victims of employment discrimination sought the services of an attorney after the most recent occurrence. B. Curran, *The Legal Needs of the Public: The Final Report of a National Survey* 135 (1977).

[5] Cleveland Regional Office and Bureau of Economics, Federal Trade Commission, *Improving Consumer Access to Legal Services: the Case for Removing Restrictions on Truthful Advertising* (1984).

[6] T. Muris & F. McChesney, *Advertising and the Price and Quality of Legal Services: The Case for Legal Clinics*, 1979 Am. B. Found. Research J. 179.

> Is likely to create an unjustified expectation about results the lawyer can achieve, or states or implies that the lawyer can achieve results by means that violate the rules of professional conduct or other law.

Similarly, subsection 2-101(C) prohibits communication that:

> Compares the quality of the lawyer's services with the quality of other lawyers' services, except as provided in Temporary DR 2-104.

(a) Temporary DR 2-101(B): Endorsements and Attorney's Results

Temporary DR 2-101(B) could be read to prohibit client endorsements and truthful communications about an attorney's record of favorable verdicts. The ABA committee comments accompanying ABA Model Rule 7.1, from which DR 2-101(B) is derived, suggest that such information is "likely to create an unjustified expectation about results the lawyer can achieve" and should be prohibited. The ABA's interpretation appears to be unnecessarily restrictive and may discourage truthful, nondeceptive communications. For example, consumers may wish to use an attorney's past results as one of several factors to consider in choosing a representative. "[I]t seems peculiar to deny the consumer, on the ground that the information is incomplete, at least some of the relevant information needed to reach an informed decision." Bates v. State Bar, 433 U.S. 350, 374 (1977).

We believe the possibility that advertisements containing client endorsements or information about past successes will create unjustified expectations is small and is probably outweighed by the potential benefits of this information to consumers. At the very least, such endorsements may enhance audience attention and retention and, consequently, increase the effectiveness of the advertisement. Many law firms list references and major clients in the Martindale-Hubbell Law Directory. The choice of the listed clients probably reflects a judgment that the representation of a major bank or corporation will suggest to potential clients that the firm can handle complicated legal problems, or cases in which large sums of money may be at risk.

To permit such major clients to endorse in an advertisement that they use a firm's legal services simply gives the general public the same information that is available to users of legal directories. Similarly, when a famous athlete or actor appears in a commercial to say truthfully that he uses a particular firm or attorney, it tells consumers that someone who can spend a substantial sum to find a good attorney, and who may have significant assets at stake, believes a particular lawyer to be effective.

Of course, many attorneys do not have large corporate or famous individual clients. But we are not aware of any reason to believe that it would be harmful for an average consumer to appear in a commercial and to say truthfully that he received prompt and satisfactory service from a particular attorney. Although many factors other than an attorney's skill can affect the outcome of a case, there is no reason to believe that consumers naively expect that the future will always resemble the past. Accordingly, we urge the Court to delete Temporary DR 2-101(B).

(b) Temporary DR 2-101(C): Comparison Claims

Temporary DR 2-101(C) prohibits any comparison of the quality of a lawyer's services with that of any other lawyer. If the term "quality" is interpreted broadly, comparisons of any kind may be prohibited or, at the least, discouraged. Information that accurately compares the particular qualities of competing law firms, however, may foster improvement and innovation in the delivery of services and may assist consumers in making rational purchase decisions. Indeed, in one sense, such consumer comparisons are the essence of competition.[7] Of course,

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[7] In its statement of policy regarding comparative advertising, the Federal Trade Commission recognized the benefits of comparative advertising and indicated concern about standards set by self-regulatory bodies that might discourage the use of such advertising:

> "On occasion, a higher standard of substantiation by advertisers using comparative advertising has been required by self-regulation entities. The Commission evaluates comparative advertising in the same manner as it evaluates all other advertising techniques... [I]nterpretations that impose a higher standard of substantiation for comparative claims than for

comparisons containing false or deceptive statements of fact, either about the advertiser or a rival, provide no benefit to consumers and can be harmful. However, such statements are already prohibited by Temporary DR 2-101(A).

We urge the Court to modify Temporary DR 2-101(C) to require only that an attorney have a reasonable basis for any material, objective claims.

(c) Temporary DR 2-102(A): Permitted Media

We are concerned that attorneys may interpret the listing of permitted media in Temporary DR 2-102(A) as exclusive and conclude that advertising media not listed are prohibited. The list of specific media that may be used in advertising could discourage innovation and the use of novel forms of expression in ways not intended by the Court, especially since the term "public media" is ambiguous. For example, the rule might be interpreted to prohibit sponsorship of museum exhibits or youth sports teams. Moreover, the specificity of the rule fails to anticipate changing technologies. If "written communication" is interpreted to refer only to physically permanent writings, advertising in computer bulletin boards, on-line directories, or similar media may be prohibited. We urge the Court to delete Temporary DR 2-102(A).

(d) Temporary DR 2-102(E): Disclaimer

Temporary DR 2-102(E) requires inclusion of a disclaimer in all advertisements that no representation is made about the quality of services or the expertise of the lawyer. The value of advertising is to help consumers to make judgments about quality and expertise, which will assist them in choosing a lawyer. As long as truthful, nondeceptive statements are made, however, no such disclaimer is necessary to protect the consumer. Almost any information in an advertisement could be interpreted as a representation about quality or expertise. The disclaimer would greatly diminish the effectiveness of advertising, and lawyers may be discouraged from advertising at all. In addition, consumers, who may want to use the information in the advertisement to make a judgment about quality and expertise, may be confused by the disclaimer as to what the information in the advertisement really means.

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unilateral claims are inappropriate and should be revised." 16 C.F.R. 14.15(c)(2) (1986).

Moreover, any disclosure requirement increases advertising costs. Advertising space or media time is limited and any disclosure reduces the net amount of time or space available to the advertiser for communicating the primary message of the advertisement. Disclosure requirements, therefore, should be used sparingly, and should not be required by the state unless there exists evidence of deception. We urge that Temporary DR 2-102(E) be eliminated.

III. Temporary DR 2-103: Direct Contact with Prospective Clients

Temporary DR 2-103 prohibits solicitation of a prospective client by telephone or in person, when a significant motive is the lawyer's pecuniary gain. The interest in pecuniary gain is legitimate and is not intrinsically harmful to consumers. Because almost any contact could include or be interpreted as including pecuniary gain as one significant motive, this prohibition is overly broad. When viewed in conjunction with DR 2-102(A), moreover, this rule could also be interpreted to prohibit targeted mailings to consumers.

More personalized forms of contact may provide many of the same benefits as advertising. Truthful, nondeceptive mail, telephone and in-person solicitation may assist consumers in learning about the availability of legal services. Both telephone and in-person solicitation may have some potential for abuse if a lawyer contacts an injured or emotionally distressed consumer. In other circumstances, however, such adverse effects are unlikely. Therefore, a comprehensive ban on all forms of solicitation is unnecessarily broad and may harm consumers. In the paragraphs that follow, we will set out our views on the proper standard to apply to different forms of solicitation.

(a) Targeted Mailings

First, lawyers should be permitted to use targeted mailings as they see fit. Written communications with prospective clients known to need legal services may help them select a lawyer. *Spencer v. Honorable Justices of the Supreme Court of Pa.*, 579 F. Supp. 880 (E.D. Pa. 1984), *aff'd mem.*, 760 F.2d 261 (3d Cir. 1985). *See In re Von Wiegen*, 63 N.Y. 2d 163, 470 N.E. 2d 838, 481 N.Y.S. 2d 40 (Ct. App. 1984), *cert. denied sub nom. Committee on Professional Standards v. Von Wiegen*, 105 S. Ct. 2701 (1985). By targeting letters to a particular audience, the lawyer can provide information to those consumers who are most likely to need legal services and who may need to have a lawyer take action expeditiously on their behalf. Those consumers are most likely to benefit from information about what services are available.

Spencer, 579 F. Supp. at 891. As the court stated in Koffler v. Joint Bar Ass'n, 51 N.Y. 2d 140, 146, 412 N.E. 2d 927, 931, 432 N.Y.S. 2d 872, 875-76 (Ct. App. 1980), cert. denied, 450 U.S. 1026 (1981):

> To outlaw the use of letters . . . addressed to those most likely to be in need of legal services . . . ignores the strong societal and individual interest in the free dissemination of truthful price information as a means of assuring informed and reliable decision making in our free enterprise system . . . .

The Seventh Circuit reasoned similarly in Adams v. Attorney Registration and Disciplinary Comm'n, 801 F.2d 968, 973 (7th Cir. 1986), that "[p]rohibiting direct mailings to those who might most desire and might most benefit from an attorney's services runs afoul of the concerns for an informed citizenry that lay at the heart of Bates." Moreover, consumers who choose to respond to such mailings incur lower search costs because they need not contact numerous lawyers to find one able to handle a specific legal problem.

Targeted mail advertising, as long as it is truthful and nondeceptive, poses little danger of consumer harm. It is unlikely that written communications will be coercive or involve intimidation or duress. In re Von Wiegen, 63 N.Y. 2d at 170, 470 N.E. 2d at 841, 481 N.Y.S. 2d at 43; Koffler, 51 N.Y. 2d at 149, 412 N.E. 2d at 933, 432 N.Y.S 2d at 877-78. When a consumer receives a letter in the mail from an attorney offering legal services, no immediate response is required and, if unwanted, the letter can easily be discarded. Such letters, however, may also communicate important information that consumers can carefully consider in making a reasoned decision about selecting a lawyer.[8] Therefore, we believe that targeted written communication should be governed by the same false and misleading standard used for other advertising. We also have no objection to prohibiting mailings to persons who have made known to the lawyer that they do not wish to receive communications from the lawyer.

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[8] See Standing Committee on Ethics and Professional Responsibility and Commission on Advertising, American Bar Association, Report to the House of Delegates 6 (1987) for a discussion of the benefits to consumers and the absence of significant potential for abuse arising from written communications. Pages 7-10 of the Report address the constitutional issues, which we do not discuss.

(b) Telephone and In-Person Solicitation

Second, we urge that the Court modify Temporary DR 2-103 to permit telephone and in-person solicitation. Like media advertising, in person solicitation may provide information to consumers that will help them ~~select~~ a lawyer. As the Supreme Court observed in Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 457 (1978), in-person contacts can convey information about the availability and terms of a lawyer's or law firm's legal services and serve the same function in this respect as print advertisements.

We recognize that abuses may result from in-person solicitation by lawyers. Injured or emotionally distressed people may be vulnerable to the exercise of undue influence when face-to-face with a lawyer, as the Supreme Court found in Ohralik, 436 U.S. at 465. We do not believe, however, that this is a justification for a broad prohibition on in-person solicitation. The Federal Trade Commission considered the concerns that underlie the Ohralik opinion when it decided American Medical Ass'n, 94 F.T.C. 701 (1979), aff'd sub nom. American Medical Ass'n v. FTC, 638 F.2d 443 (2d Cir. 1980), aff'd mem. by an equally divided court, 455 U.S. 676 (1982). After weighing the possible harms and benefits to consumers, the ~~FTC~~ ordered the AMA to cease and desist from banning solicitation, but permitted the AMA to proscribe uninvited, in-person solicitation of persons who, because of their particular circumstances, are vulnerable to undue influence.

In-person solicitation by lawyers usually does not involve the exercise of undue influence. Lawyers often encounter potential clients at meetings of political and business organizations and at social events. Indeed, many lawyers traditionally have built their law practices through such contacts. If a lawyer discusses his or her legal services with a potential client under such circumstances, no undue influence is likely to be involved. In such a situation, the potential client need not respond immediately and can subsequently select a lawyer should a need for legal services arise.

Accordingly, we urge that Temporary DR 2-103 be modified to prohibit (1) uninvited, in-person solicitation of persons who, because of their particular circumstances, are vulnerable to undue influence and (2) solicitation of persons who have made known to the lawyer that they do not want to be contacted by the lawyer. False or deceptive solicitation, as already indicated, should also be prohibited. Such rules would protect consumers while, at the same time, allowing them to receive information about available legal services.

Telephone solicitation similarly can convey useful information to consumers, and it may present even less risk of the exercise of undue influence than does in-person solicitation. In most circumstances, telephone solicitation appears unlikely to result in consumer harm. Consumers are accustomed to telephone marketing. They receive calls from persons offering the sale of various goods and services, conducting surveys about the products and services consumers use, seeking contributions to charities, and requesting support for political candidates. Consumers can easily terminate such conversations if they wish.

On the other hand, telephone solicitation is in some respects similar to in-person solicitation in that a verbal exchange takes place; a lawyer might be able to persuade a vulnerable person to hire the lawyer when a non-vulnerable person would not hire him or her under the same circumstances. Moreover, there may be reasons why restrictions on telephone solicitation not appropriate for other professionals may appropriately be applied to lawyers. Certainly, false and deceptive telephone solicitation and telephone solicitation of persons who have made known to the lawyer that they do not want to receive calls from the lawyer may appropriately be prohibited. Although the standard for uninvited, in-person solicitation may also be appropriate here, we are not yet ready to conclude that it should be applied to telephone solicitation. But certainly the broad ban on telephone solicitation contained in Temporary DR 2-103 is unnecessarily restrictive.

IV. Temporary DR 2-104: Communication of Fields of Practice

Temporary DR 2-104 prohibits a lawyer from stating or implying that he or she is a specialist. Such a rule would prevent a lawyer from using the word "specialist" in making a truthful claim that he or she has developed skills or focused his or her practice on an area of the law. Yet use of this term may be the clearest, most efficient way to communicate that information. It is not clear that a claim that one is a "specialist" would be understood by lay persons to imply that a lawyer has obtained formal recognition as a specialist. The prohibition of false claims of certification further diminishes the likelihood of such a public misunderstanding. Temporary DR 2-104 could also be interpreted to prohibit a wide variety of truthful statements about experience and special training. For example, a true statement that an attorney is a member of an organization of trial lawyers might be interpreted by some as an implied claim of specialization, even though it also informs consumers that the attorney has sufficient interest in trial advocacy to join the organization and has access to the organization's training and materials. There are many ways to obtain expertise, and information that an attorney has special experience or skills in a particular field is clearly useful to consumers needing help in that field. Nor do we believe that advertising as a "specialist" would create an unjustified expectation about the results that a lawyer can achieve, any more than identifying oneself as a cardiovascular surgeon generates an expectation that every operation will be a success. We recommend that the Court remove all prohibitions against truthful and nondeceptive claims, express or implied, that a lawyer is a specialist.

V. Temporary DR-3-102(A) and 3-103(A) and (C)(2): Professional Independence of a Lawyer

Temporary DR 3-102(A) and 3-103(A) and (C)(2) prohibit a lawyer from forming a partnership or sharing legal fees, except under limited circumstances, with a nonlawyer, or from practicing in a professional corporation or other business organization authorized to practice law for a profit if a nonlawyer owns an interest in the organization or is an officer or director. The rules limit the ability of lawyers to establish multidisciplinary practices with other professionals, such as psychologists, nurses, or accountants, to deal efficiently with both the legal and nonlegal aspects of specific problems.

In *American Medical Association*, 94 F.T.C. 701, 1017-18 (1979), *aff'd*. 638 F.2d 443 (2d Cir. 1980), *aff'd* mem. *by an equally divided court*, 455 U.S. 676 (1982), the Federal Trade Commission found that the AMA's ethical restrictions on the formation of professional associations with nonphysicians had an adverse effect on competition. The AMA's form of practice restrictions precluded a wide variety of professional ventures and economically efficient business formats, such as health maintenance organizations and prepaid health care plans. The Commission concluded that the prohibitions were much broader than needed to prevent non-physician influence over medical procedures or consumer deception about the skills of a non-physician partner or associate. Temporary DR 3-102(A) and 3-103(A) and (C)(2) similarly limit potentially procompetitive professional ventures and innovative business formats. Temporary DR 3-103(B) and (C)(1) alone should adequately preserve the lawyer's independent professional judgment. Therefore, we recommend that the Committee delete Temporary DR 3-102(A) and 3-103(A) and (C)(2).

VI. Conclusion

The Temporary Rules approved by the Court in October 1985 gave lawyers a greater opportunity to disseminate information about legal services to consumers than previously. We urge that the Court eliminate other unnecessary restrictions on competition among lawyers by:

(1) deleting Temporary DR 2-101(D) and 2-112;

(2) deleting Temporary DR 2-101(B);

(3) modifying Temporary DR 2-101(C) to require only that an attorney have a reasonable basis for any material, objective claims;

(4) deleting Temporary DR 2-102(A);

(5) deleting Temporary DR 2-102(E);

(6) modifying Temporary DR 2-103 to eliminate (a) the broad ban on telephone solicitation except for false and deceptive solicitation and solicitation of persons who have expressed a desire not to be contacted and (b) the restrictions on in-person solicitation except for false and deceptive solicitation and solicitation of persons who, because of their particular circumstances, are vulnerable to undue influence or who have expressed their wish not to be contacted;

(7) modifying Temporary DR 2-104 to allow express and implied claims of specialty; and

(8) deleting Temporary DR 3-102(A) and 3-103(A) and (C)(2).

We appreciate having had the opportunity to present these views.

Sincerely yours,

Harold E. Kirtz

Harold E. Kirtz
Assistant Director
Atlanta Regional Office

Paul K. Davis HCK

Paul K. Davis
Director
Atlanta Regional Office

North American Philips Corp. (Black Pro razor) C-3105
End of show cause proceedings

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
[illegible]

FOR YOUR INFORMATION.........September 25, 1984

The Federal Trade Commission will continue to require four companies that market electric shavers for black men to support their advertising claims with two well-controlled clinical tests, it announced today. In ending show-cause proceedings, the Commission declined to modify consent orders issued in 1983 and 1981 to permit substitution of one well-controlled clinical test for the existing two-test requirement.

The proceedings began in March of last year, when the Commission issued show-cause orders to North American Philips Corp. (Norelco), manufacturer of the "Black Pro" shaver; Norelco's ad agency, McCaffrey and McCall; Sperry Corp., manufacturer of the "Black Man's Shaver"; and Sperry's ad agency, DKG Advertising Inc.

The Commission had issued consent orders against Norelco and its ad agency in March 1983 prohibiting them from claiming that the "Black Pro" shaver — or any other electric shaver, device or drug — could relieve or cure the medical condition known as "razor bumps," unless they had results from two well-controlled clinical tests to support such claims. In July of 1981, the Commission had issued similar consent orders against Sperry and DKG Advertising.

The consent orders settled charges that the firms had falsely and deceptively advertised that use of the shavers could cure or alleviate "razor bumps".

"Razor bumps" is a skin condition that affects as many as 50 percent of black men. The condition occurs when curly facial hair grows back into the skin after shaving, resulting in ingrown hairs, infection and, potentially, facial scarring.

In terminating the show-cause proceedings, the Commission concluded that, although other circumstances might warrant the use of a different level of substantiation, two clinical studies were required here. The use of two tests, according to the Commission, will reduce the risk of the firms making inaccurate claims about their shavers in the future. The FTC also stated that the cost savings of performing one test, as opposed to two, would be modest since the single-test method would require additional procedural safeguards for reliability.

In addition, the agency noted that the companies' past conduct, as alleged in the complaints, of making false and unsubstantiated claims on the basis of flawed and inadequate testing, warranted more rigorous substantiation requirements.

All four companies are based in New York.

Copies of the orders ending the show-cause proceedings are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1848.

# # #

MEDIA CONTACT: Mario A. Baldassari, Office of Public Affairs,
202-523-1848

STAFF CONTACT: Elizabeth T. Guarino, Bureau of Consumer Protection,
202-376-8617

(Docket No. C-3166, 3166, 3068, 3069)

(renora)

North American Philips Corp. (Black Pro razor) show cause orders

FTC news

Federal Trade Commission Washington, D.C. 20580

FOR IMMEDIATE RELEASE: March 11, 1983

FTC SEEKS VIEWS ON WHETHER ONE TEST IS ENOUGH TO BACK CLAIMS THAT "BLACK PRO," "BLACK MAN'S" SHAVERS OR OTHER PRODUCTS TREAT RAZOR BUMPS

North American Philips Corp. (Norelco) and its advertising agency, McCaffrey and McCall Inc., may not claim that the "Black Pro" shaver can cure razor bumps, a painful skin condition that results from shaving and particularly affects black men, under separate final Federal Trade Commission consent orders announced today.

However, the FTC is also reopening the 1981 case to seek comments on a provision requiring at least two well-controlled clinical studies to substantiate razor-bump effectiveness claims for any of Norelco's products. The FTC has issued "show-cause" orders to the company and its ad agency concerning a proposal to change the requirement to only one test. The orders require the companies to "show cause" within 30 days why the order modification would not be in the public interest.

The show-cause orders also ask for comments from concerned experts, affected companies and other interested persons about the appropriateness and requirements of a one-test standard. And the orders seek comments on whether specific criteria are needed to ensure that a single test is reliable.

In a statement explaining the show-cause orders, the FTC says it "has recently become aware of the existence of reliable expert opinion to the effect that one clinical study, if properly conducted, can provide a reasonable basis for future razor bump efficacy claims." It also said it "recognizes that requiring excessive levels of substantiation may unduly limit the ability of sellers to communicate useful information to consumers."

Complaints issued with the consents alleged Norelco and McCaffrey and McCall falsely and deceptively claimed that when a customer uses the shaver, "Razor bumps go away and stay away as proven in tests at a leading black university." The FTC charged the Black Pro shaver cannot cure the condition, and the university tests "do not prove that the Black Pro shaver will cure the condition of razor bumps." The complaints also charged the companies lacked a reasonable basis for claims that the shaver is an effective treatment for razor bumps.

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The FTC also issued "show-cause" orders to Sperry Corp. and its ad agency, DKG Advertising Inc., concerning 1981 consent orders with them. They allegedly made similar razor-bump cure claims for Sperry's Black Man's Shaver and also were required to have at least two tests to support effectiveness claims.

In addition, the Commission is releasing a letter to Sperry responding to its complaint that the FTC treated it unfairly. Sperry was required to provide restitution to Black Man's Shaver customers, yet Norelco was not required to do so for its Black Pro customers. The FTC, in explaining its decision, said that at the time the Norelco case was settled, "the Commission determined that [Norelco] was not in a similar position to attempt communication with large numbers of past purchasers."

The Commission voted 3-2 to issue the consent orders and 3-2 to issue the show-cause orders. Commissioners Patricia P. Bailey and Michael Pertschuk dissented in both decisions. A motion to simply issue the consent orders without the show-cause orders was defeated 2-3, with Chairman James C. Miller III and Commissioners David A. Clanton and George W. Douglas in the majority.

Bailey's statement objected to the proposal, to be submitted for public comment, that would require only one clinical test. "[F]inal acceptance of these orders, involving in effect a medical device that causes rather than alleviates a serious medical problem, has been delayed for over a year while an exhaustive study has been made of the 'costs' which might result from a two-test requirement. A second test would cost $20,000, a minimal amount when compared to actual or potential sales. I do not believe this is a close case. I believe it clearly is one for which two tests should be required."

Pertschuk also questioned the reasoning behind the change to a one-test requirement. He said that "the costs of further review and introspection about the 'perfect' level of substantiation for this type of product far exceed any benefits from doing so. The real loss is that the public is not protected by a final order and other cases are left untended while the Commission ties itself in analytical knots."

Copies of the consent orders, the show-cause orders, the Commission statement explaining the show-cause orders, the dissenting statements and the FTC letter to Sperry are available from the FTC's Public Reference Branch, Room 130, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Janet Bass, Office of Public Affairs,
202-523-1848

STAFF CONTACT: Mitchell Paul, Bureau of Consumer Protection,
202-724-1464

(File No. 812 3000)

[Shaver]

North American Philips Corp. C-3103 Final consent 3/7/

'Black Pro razor)

FTC news

Federal Trade Commission Washington, D.C. 20580

HOLD FOR RELEASE UNTIL: Wednesday, September 23, 1981

NORTH AMERICAN PHILIPS AND AD AGENCY TO STOP ADVERTISING THAT THE "BLACK PRO" SHAVER CURES MEN'S RAZOR BUMPS, UNDER FEDERAL TRADE COMMISSION CONSENT AGREEMENT

Unfounded Ad Claims for Other Consumer Products Barred

North American Philips Corp. and its advertising agency, McCaffrey and McCall Inc., may not claim that the "Black Pro" shaver will cure razor bumps, a skin condition affecting black men, and may not make other effectiveness claims regarding razor bumps without having reliable scientific or medical evidence to support it, under separate consent agreements announced today by the Federal Trade Commission.

According to complaints issued with the consents, Philips and the ad agency claimed, among other things, that by using the shaver, "Razor bumps go away and stay away as proven in tests at a leading black university." The complaint says the claim is false and deceptive and the tests used did not provide a reasonable basis.

Razor bumps occur when curly facial hair grows back into the skin after shaving.

Under the proposed consent orders, Philips and McCaffrey and McCall may not advertise that the "Black Pro" shaver or any other electric shaver, drug or device will cure razor bumps; and they may not state that tests prove the product will cure the condition. Also, the proposed orders ban claims that razor bumps will be reduced, minimized or effectively treated by using the shaver, unless at the time of each claim, competent scientific or medical evidence is used to back up the statement.

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NOTE: These consent agreements are for settlement purposes only and do not constitute an admission by the companies that they violated the law. When issued by the Commission on a final basis, a consent order carries the force of law with respect to future actions. A violation of such an order may result in a civil penalty of up to $10,000.

In addition, in advertisements for Philips' electric or cordless shavers, microwave ovens and toaster ovens, both companies are prohibited from:

- Making statements concerning performance or benefits unless the companies possess and rely on competent evidence that substantiates the claim.
- Presenting evidence, such as tests or demonstrations, that do not actually support or prove statements concerning performance or benefits of the product.
- Referring to any evidence, such as tests, reports or experiments, unless it has been designed and analyzed scientifically and its purpose and results are fairly and accurately represented.

The complaints charged that Philips and McCaffrey and McCall made such false and misleading statements as "[North American Philips Corporation] ... and a leading black university have found a dramatic cure for your shaving problems.... Even in daily shaving." Another allegedly deceptive statement was "These unretouched photos prove that after shaving for six weeks with the ... Black Pro, your skin can be free of razor bumps."

Ads for the shaver appeared in national magazines, newspapers and on radio.

Last May, Sperry Corp. and DKG Advertising Inc. agreed to similar consents concerning the "Black Man's Shaver."

North American Philips Corp. and McCaffrey and McCall are located in New York.

The consent agreements will be the subject of public comment for 60 days, until Nov. 23, after which the Commission may issue them as final or withdraw acceptance.

Copies of the complaints, the consent agreements, the Commission's proposed orders and analyses of the agreements may be obtained from the FTC's Public Reference Branch, Room 130, 6th Street and Pennsylvania Avenue Northwest, Washington, D.C. 20580; 202-523-3598. Comments may be directed to the Office of the Secretary at the same address.

# # #

MEDIA CONTACT: Janet Bass, Office of Public Affairs,
202-523-1848

STAFF CONTACT: Mitchell Paul, Bureau of Consumer Protection,
202-724-1483

(File No. 812-3000)

[RAZOR]

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: July 28, 1983

FTC CHALLENGES ADS CLAIMING DIET SUPPLEMENT "DAILY GREENS" REDUCES CHANCES OF CANCER

Unsubstantiated advertising claims touting the dietary supplement Daily Greens as associated with a reduction in the incidence of cancer in humans are unfair and deceptive, the Federal Trade Commission charged in a complaint today. In addition, PharmTech Research Inc., the product's manufacturer, represented falsely that a National Academy of Sciences report supports that claim and another that the product helps build biological defenses, the FTC alleged.

The Commission also is seeking a preliminary injunction in federal district court to halt the product's current nationwide print and broadcast advertising campaign.

Daily Greens are pills containing dehydrated vegetable matter and some vitamins and minerals. PharmTech based its ad claims on a 1982 National Academy of Sciences' National Research Council report. That report concluded that eating vegetables such as brussels sprouts, cabbage and carrots could reduce the incidence of some types of cancer in humans. The report, however, limited its findings to fresh, unprocessed vegetables and specified that its conclusions are not applicable to dietary supplements.

According to the complaint, one ad for Daily Greens claims: "Help your body defend itself" with Daily Greens. Another ad for Daily Greens states: "Cabbage, Brussels Sprouts, Carrots, Cauliflower, Spinach and Broccoli vs. Cancer." And another notes the report's results and declares: "Thanks to the process of dehydration, Daily Greens allow you to eat cruciferous vegetables regularly, with the convenience of a food supplement."

The complaint charged PharmTech with two counts of false advertising. The FTC said PharmTech misrepresented that the NAS findings support the claim that Daily Greens or other similar food supplements are associated with a reduction in human cancer. PharmTech also allegedly misrepresented that the report's findings support a claim that Daily Greens may help consumers build important biological defenses. And the Commission charged PharmTech does not have a reasonable basis to support its claim that the product is associated with a reduction in the incidence of some human cancers. Therefore, the FTC said that claim is unfair and deceptive.

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If an administrative law judge upholds the charges, the FTC could issue an order prohibiting PharmTech from representing, contrary to fact, that the 1982 Report titled Diet, Nutrition, and Cancer, supports the claim that use of Daily Greens is associated with a reduction in the incidence of any type of cancer. The order could also prohibit misrepresenting any scientific test or research article. And the order could prohibit PharmTech from making any representation concerning the health benefit of any such product unless it relies on competent scientific evidence.

PharmTech has offices in San Francisco.

Copies of the complaint and notice of contemplated relief (proposed order) are available from the FTC's Public Reference Branch, Room 130, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580; 202-523-3598, TTY 202-523-3638.

# # #

MEDIA CONTACT: Janet Bass, Office of Public Affairs, 202-523-1848

STAFF CONTACT: Andrew Sacks, Bureau of Consumer Protection, 202-724-1525

(File No. 832 3174)

[Greens]

Under the agreement, PharmTech may not misrepresent the results of any scientific test, research article or other scientific opinion or data.

The agreement also prohibits PharmTech from claiming Daily Greens provides any health benefit unless the company has reliable and competent scientific evidence substantiating the claim.

PharmTech must maintain accurate records of all materials relied upon in disseminating any representation covered by the order and of all information of which it has knowledge that contradict such representations.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues it on a final basis, a consent order carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

The proposed order will be subject to public comment for 60 days, until April 16, after which the Commission will decide whether to make it final.

Comments may be addressed to the Secretary, Federal Trade Commission, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580.

Copies of the proposed order are available from the FTC's Public Reference Branch, Room 130, same address as above, 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Janet Bass, Office of Public Affairs,
202-523-1848

STAFF CONTACT: Andrew Sacks, Bureau of Consumer Protection,
202-376-8648

(Docket No. 9168)

(DailyG)

FTC news

Federal Trade Commission Washington, D.C. 20580

FOR IMMEDIATE RELEASE: July 28, 1983

FTC CHALLENGES ADS CLAIMING DIET SUPPLEMENT "DAILY GREENS" REDUCES CHANCES OF CANCER

Unsubstantiated advertising claims touting the dietary supplement Daily Greens as associated with a reduction in the incidence of cancer in humans are unfair and deceptive, the Federal Trade Commission charged in a complaint today. In addition, PharmTech Research Inc., the product's manufacturer, represented falsely that a National Academy of Sciences report supports that claim and another that the product helps build biological defenses, the FTC alleged.

The Commission also is seeking a preliminary injunction in federal district court to halt the product's current nationwide print and broadcast advertising campaign.

Daily Greens are pills containing dehydrated vegetable matter and some vitamins and minerals. PharmTech based its ad claims on a 1982 National Academy of Sciences' National Research Council report. That report concluded that eating vegetables such as brussels sprouts, cabbage and carrots could reduce the incidence of some types of cancer in humans. The report, however, limited its findings to fresh, unprocessed vegetables and specified that its conclusions are not applicable to dietary supplements.

According to the complaint, one ad for Daily Greens claims: "Help your body defend itself" with Daily Greens. Another ad for Daily Greens states: "Cabbage, Brussels Sprouts, Carrots, Cauliflower, Spinach and Broccoli vs. Cancer." And another notes the report's results and declares: "Thanks to the process of dehydration, Daily Greens allow you to eat cruciferous vegetables regularly, with the convenience of a food supplement."

The complaint charged PharmTech with two counts of false advertising. The FTC said PharmTech misrepresented that the NAS findings support the claim that Daily Greens or other similar food supplements are associated with a reduction in human cancer. PharmTech also allegedly misrepresented that the report's findings support a claim that Daily Greens may help consumers build important biological defenses. And the Commission charged PharmTech does not have a reasonable basis to support its claim that the product is associated with a reduction in the incidence of some human cancers. Therefore, the FTC said that claim is unfair and deceptive.

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If an administrative law judge upholds the charges, the FTC could issue an order prohibiting PharmTech from representing, contrary to fact, that the 1982 Report titled Diet, Nutrition, and Cancer, supports the claim that use of Daily Greens is associated with a reduction in the incidence of any type of cancer. The order could also prohibit misrepresenting any scientific test or research article. And the order could prohibit PharmTech from making any representation concerning the health benefit of any such product unless it relies on competent scientific evidence.

PharmTech has offices in San Francisco.

Copies of the complaint and notice of contemplated relief (proposed order) are available from the FTC's Public Reference Branch, Room 130, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580; 202-523-3598, TTY 202-523-3638.

# # #

MEDIA CONTACT: Janet Bass, Office of Public Affairs, 202-523-1848

STAFF CONTACT: Andrew Sacks, Bureau of Consumer Protection, 202-724-1525

(File No. 832 3174)

[Greens]

Estee Corp. C-3166 11/16/83

FTC

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: August 31, 1983

SPECIALTY FOODS MAKER AGREES NOT TO MISREPRESENT ITS PRODUCTS' SUITABILITY FOR DIABETICS, UNDER PROPOSED FTC CONSENT ORDER

Estee Corp., a leading manufacturer of health-related special foods, has agreed not to advertise that its foods are useful or appropriate for diabetics' diets without adequate substantiation, the Federal Trade Commission announced today. Under the consent agreement, the company will also pay $25,000 in consumer redress in the form of research grants to the American Diabetes Association or the Juvenile Diabetes Foundation.

Estee produces a variety of dessert and snack foods, such as cookies and candies, sold chiefly to diabetics. The foods do not contain sucrose, or "table sugar," but are instead sweetened with fructose, sorbitol or high fructose corn syrup (HFCS).

The agreement settles charges Estee's magazine and label advertisements misled consumers by claiming the sweeteners in its foods "have been accepted by the [American Diabetes Association] and the [Food and Drug Administration] as being useful in the diets of diabetics on the advice of a physician." According to a complaint prepared as part of the agreement, neither the FDA nor the ADA has concluded that HFCS is useful for diabetics. For fructose and sorbitol, the FDA also has made no conclusions, while the ADA's conclusions are subject to significant qualifications.

According to the Commission, Estee lacked a reasonable basis for its unqualified statements that its fructose-sweetened and sorbitol-sweetened foods are appropriate for diabetics because these foods should not be eaten in more than limited amounts by diabetics and should not be eaten by out-of-control diabetics. Also, many of these foods are not useful for weight-control, an important consideration for many diabetics.

The complaint charged that Estee falsely advertised that its "fructose" foods are all sweetened with fructose, when in fact some are sweetened with HFCS. The Commission alleged Estee did not have a reasonable basis for its claims that these HFCS-sweetened foods are appropriate for diabetics and that HFCS has the same characteristics as fructose.

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The complaint also charged that Estee's ads promoted the company's products as "dietetic" or reduced-calorie foods, when in fact many of the advertised foods did not contain significantly fewer calories than sucrose-sweetened products. Consequently, contrary to what the company's ads implied, these foods are not appropriate for weight loss or weight control diets.

In addition, according to the Commission, although Estee advertised that its products do not contain sugar, many of the foods are sweetened with fructose or high fructose corn syrup, both of which are sugars.

The proposed consent order announced today prohibits Estee from making misrepresentations about its products. The company must have reliable scientific evidence for claims that its foods affect blood sugar levels and for health-related claims that its foods are suitable for diabetics or hypoglycemics. In addition, when advertising that a food is recommended for diabetics or hypoglycemics, the company must disclose the identity of the endorser and any material limitations on that endorsement. Also, whenever a food is advertised as appropriate for diabetics, Estee's ads must state that food "is not a reduced calorie food" if that food is not defined as reduced calorie under FDA regulations.

Under the agreement, the company may not misrepresent the identity of a sweetener or the truthfulness of any endorsement, and may not claim that fructose and HFCS are not sugars. Estee also will not state that its foods are reduced in calories compared to other foods or are appropriate for weight-control unless such statements are true.

The company must pay the $25,000 for diabetes research within two years. Estee Corp. is located in Parsippany, N.J.

The consent agreement is scheduled to appear in the Federal Register Sept. 2. It will be subject to public comment for 60 days, until Nov. 1, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580. Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Mary Ann Miller, Office of Public Affairs,
202-523-1849

STAFF CONTACT: Robert C. Cheek, Bureau of Consumer Protection,
202-724-0726

(File No. 802-3165) (estee)

Also, under the agreement, they are prohibited from advertising that an emergency escape mask protects the wearer from carbon monoxide; provides breathable air for 20 minutes, or any other period of time; or permits normal breathing unless it has reliable, scientific tests substantiating the claim.

And the company has agreed to cover with a label all references on current packaging to the mask's supposed ability to protect against carbon monoxide and provide filtered breathing for 20 minutes.

The FTC issued a separate, similar complaint and consent agreement for Monte Proulx, who helped sell the masks.

Emergency Devices has headquarters in San Francisco.

The consent agreement will be subject to public comment for 60 days, until Oct. 25, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580.

Copies of the agreements, the complaints and analysis of the agreements are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Janet Bass, Office of Public Affairs,
202-523-1848

STAFF CONTACT: Collot Guerard, Bureau of Consumer Protection,
202-724-1499

(File No. 822 3139)

[Mask]

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: September 16, 1983

BRASWELL PROHIBITED PERMANENTLY FROM ADVERTISING BALDNESS "CURES" WITHOUT FDA APPROVAL OF PRODUCT, UNDER FEDERAL TRADE COMMISSION CONSENT JUDGMENT

Also Agrees to Pay $610,000 in Civil Penalties

Braswell Inc., its director, A. Glenn Braswell, and its subsidiaries are barred permanently from representing that any product or service will cure or prevent hereditary baldness, under a court-filed consent judgment with the Federal Trade Commission. The parties also agreed to pay $610,000 in civil penalties.

Under the judgment, Braswell is enjoined permanently from:

-- Representing that any product or service will cure, treat, prevent or overcome male pattern or hereditary baldness or, in such cases, cause new hair to grow. However, the company may make these claims if the Food and Drug Administration has approved the product or service.

-- Representing that any product or service will cure, treat, prevent or overcome baldness without disclosing clearly and conspicuously Braswell's product or service is not effective for male pattern or hereditary baldness or new hair growth.

-- Misrepresenting the results of any test or study.

-- Making performance or efficacy claims for any product or service, unless Braswell has reliable scientific evidence to substantiate the claim.

  - For products or services relating to baldness, cellulite, anti-aging or sexual performance, Braswell must have one well-controlled double-blinded clinical study. For all other products or services, the company must rely on evidence recognized by qualified medical and scientific opinion.

(More)

- -- Offering a satisfaction or money-back guarantee, without disclosing clearly its terms and conditions.
- -- Failing to honor satisfaction or money-back guarantees.
- -- Violating any provision of the FTC's Mail Order Merchandise Rule.

The consent judgment names A. Glenn Braswell, Braswell Inc., Cosvetic Laboratories Inc., Quest Research Inc., and Standard Research Laboratories Inc. and its president, Charles L. Richardson.

The Commission explained in a statement that it was not seeking consumer redress because of the difficulty and expense in identifying those consumers injured by the alleged practices. The statement continued that the "civil penalty imposed here together with the injunctive relief obtained will assure that future consumer injury is avoided."

The Commission voted 4-1 to accept the judgment. Commissioner Patricia P. Bailey dissented from acceptance of the settlement because, in her view, the judgment's advertising substantiation requirements are inadequate to protect consumers from deceptive product performance claims.

Commissioner Michael Pertschuk voted to accept the settlement because of the civil penalty and injunctive relief obtained, but issued a statement explaining that he was not entirely satisfied with the consent. "In my judgment, the substantiation requirements are neither as tough as they ought to be for the kinds of claims made by these defendants, nor are they consistent with traditional Commission ad substantiation policy."

The FTC's Atlanta Regional Office handled the investigation.

The Justice Department filed the judgment on the FTC's behalf in U.S. District Court for the Northern District of Georgia, Atlanta Division.

Copies of the judgment, the reasons-for-settlement statement and Commissioner Pertschuk's statement are available from the FTC's Public Reference Branch, Room 130, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3598.

# # #

MEDIA CONTACT: Janet Bass, Office of Public Affairs, 202-523-1848

STAFF CONTACT: David R. Flowerree, Atlanta Regional Office, 404-881-4836

(File No. 792 3165) [Bald]

FTC NEWS

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: October 25, 1983

POLLENEX PURE AIR "99" AIR CLEANER/DEODORIZER DOES NOT REMOVE MOST TOBACCO SMOKE, DUST OR POLLEN AS CLAIMED, FEDERAL TRADE COMMISSION CHARGES

The Pollenex Pure Air "99" Air Cleaner/Deodorizer does not eliminate or remove most tobacco smoke, ragweed pollen or dust, as advertised, the Federal Trade Commission charged in a complaint today.

According to the complaint, Associated Mills' ads claim the unit eliminates, cleans the air of or removes most of the tobacco smoke from household air. In one television ad, Pollenex spokesman George Burns says, "When I smoke cigars at home my friends never object. Because I've got a Pollenex Pure Air '99.' ... Smoke goes in here ... clean air comes out here."

However, the complaint charges the ads are false and misleading. The Pure Air "99" does not eliminate all or even most of the tobacco smoke from a room. Independent tests show the unit can remove at best no more than 12 percent of tobacco smoke from indoor air under normal household conditions, the complaint charges.

Associated Mills also claims its unit "removes smoke, pollen and dust ... everything but your relatives!" It advertises the product will remove "99 percent of ragweed pollen" and 80 percent of the dust in a household. But, the FTC charged, the Pure Air "99" cannot remove such high quantities of the indoor pollutants.

The company further claimed the unit effectively filters all the air in a 14' x 18' room in approximately 25 minutes. The complaint alleges the product cannot filter the air in a room that size in 25 minutes or even in an hour.

In addition, Associated Mills directly represented or implied it had a reasonable basis for the ad claims. The FTC charged the company did not have adequate substantiation, because it did not conduct appropriate tests or use generally accepted procedures to apply test results to advertised room conditions.

(More)

If an administrative law judge upholds the charges, and the Commission affirms the decision, the Commission could order Associated Mills to stop falsely advertising the Pure Air "99"'s effectiveness and the effectiveness of other indoor air cleaning products. The Commission could further require the company to have a reasonable basis, consisting of scientific tests or other competent evidence, for claims for any indoor air cleaning product.

According to FTC staff, Associated Mills Inc. sold more than 1.2 million Pure Air "99"s in 1981, for around $35 each. The relatively new indoor air cleaning industry as a whole sold more than six million units in 1982.

Associated Mills is based in Chicago. The FTC is not charging spokesman George Burns in connection with this matter.

The FTC filed a similar complaint against Rush-Hampton Industries Inc., maker of the "Ecologizer CA/90" indoor air cleaner, last July.

The Commission issues a complaint when it has "reason to believe" that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

Copies of the complaint are available from the Public Reference Branch, Room 130, Federal Trade Commission, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-523-1892

STAFF CONTACT: Mitchell Paul, Bureau of Consumer Protection, 202-724-1464

(File No. 822 3170)

(POLLNX)

Associated Mills D. 9169 Final
Consent 7/23/85

FTC NEWS

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: January 31, 1985

POLLENEX AND ECOLOGIZER AIR CLEANER MAKERS, AD AGENCY MUST NOT FALSELY CLAIM THEIR PRODUCTS CAN REMOVE AIR POLLUTANTS, UNDER FTC CONSENT AGREEMENTS

FTC Seeks Comments on Agreements with Associated Mills, Rush Hampton Industries Inc. and Young & Rubicam/Zemp Inc.

The manufacturers of two household indoor air cleaners, and the advertising agency for one of them, may not falsely represent the ability of their products to remove tobacco smoke or other pollutants from the air, under terms of consent agreements the Federal Trade Commission issued today for public comment.

The consent agreements settle separate 1983 administrative complaints the FTC issued against Associated Mills, maker of the Pollenex Pure Air "99" Air Cleaner/Deodorizer, and Rush-Hampton Industries Inc., marketer of the Ecologizer CA/90 Series 2000 Air Treatment System. The FTC charged the companies violated the law by making false, misleading and unsubstantiated advertising claims that their products could remove indoor air pollutants, including tobacco smoke, dust and pollen, and that the Ecologizer could also remove formaldehyde gas.

In a complaint released with a separate consent agreement with Young & Rubicam/Zemp Inc., Rush-Hampton's advertising agency, the FTC alleges the ad agency violated the law by making false claims about the Ecologizer.

Under the consent agreements, Rush-Hampton, Associated Mills and Young & Rubicam/Zemp Inc. have agreed not to misrepresent the ability of the Ecologizer or Pollenex air cleaners, or of any appliance or equipment, to clean household air.

In addition, the companies have agreed not to make any performance claims for air cleaning appliances or equipment unless they have competent and reliable tests substantiating the claims. In a separate document accompanying the agreement, Associated Mills indicated that, in developing substantiation, it will use tests conducted according to a protocol designed for the Association of Home Appliance Manufacturers.

The consent agreement with Associated Mills specifically prohibits the company from misrepresenting that the Pollenex Pure Air "99" Air Cleaner/Deodorizer Model 699 removes tobacco smoke, ragweed pollen or dust from the air people breathe. Under the consent agreement, the company must not falsely claim that the Model 699 effectively filters all the air in a 14- by-18-foot room in less than an hour.

(More)

The consent agreements with Rush-Hampton and Young and Rubicam/Zemp Inc. prohibit them from misrepresenting that the Ecologizer CA/90 Series 2000 Air Treatment System removes substantially all formaldehyde gas, tobacco smoke, household dust or pollen from the air. Under the consent, the companies must not falsely claim that the Series 2000 Air Treatment System effectively filters all the air in a 14-by-18-foot room in less than an hour.

According to FTC staff, in 1981 the relatively new indoor air cleaning industry as a whole sold more than 3.5 million units. In 1981 Rush-Hampton sold about 680,000 Ecologizers at a cost of $20 to $40, and Associated Mills sold more than 1.2 million Pure Air "99s" for about $35 each.

Rush-Hampton is located in Longwood, Fla., and Young & Rubicam/Zemp Inc. in St. Petersburg, Fla. Associated Mills is based in Chicago. In April 1984 Rush-Hampton sold its Ecologizer CA/90 air and water purification business to Talley Industries Inc., a Phoenix, Ariz., multi-industry company.

The consent agreements are scheduled to appear in the Federal Register Tuesday, Feb. 5. They will be subject to public comment for 60 days, until April 8, after which the Commission will decide whether to make them final.

Consent agreements are for settlement purposes only and do not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-523-1891

STAFF CONTACT: Judith Wilkenfeld, Bureau of Consumer Protection, 202-376-8648

FTC File Nos:
    Rush-Hampton Inc. — 822 3171
    Associated Mills — 822 3170

[RushAssoc]

Associated Mills, Inc. D. 9169
Final consent 7/23/85

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 523-3830

FOR YOUR INFORMATION..................August 5, 1985

The Federal Trade Commission has given final approval to the following consent agreements that it had provisionally accepted and placed on the public record for comment:

- Associated Mills Inc., maker of the Pollenex Pure Air "99" Air Cleaner/Deodorizer. The consent agreement settles charges the company made false, misleading and unsubstantiated advertising claims that its product could remove indoor air pollutants, including tobacco smoke, dust and pollen. The consent agreement was placed on the public record for comment Jan. 31 and the final order issued July 23. (Docket No. 9169)
- Decorating Products of Central Florida, a regional trade association for the wallcovering industry. The consent agreement settles charges that the group conspired to fix prices and restrain competition in the sale of wallpaper. The consent agreement was placed on the public record for comment May 14 and the final order issued July 26. (Docket No. C-3159)
- Hawaii Dental Service Corp., a dental insurance plan. The consent agreement settles charges the group acted to limit competition among dentists in the state. The consent agreement was placed on the public record for comment April 29 and the final order issued July 26. (Docket No. C-3158)

A consent order is for settlement purposes only and does not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future violations. Each violation of such an order may result in a civil penalty of up to $10,000.

A news release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and final orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies of the releases and orders are available from the Office of Public Affairs, Room 496, same address; 202-523-1848.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-523-1848

(secondstep)

Estee Corp. C-3166 11/16/83

FTC

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: August 31, 1983

SPECIALTY FOODS MAKER AGREES NOT TO MISREPRESENT ITS PRODUCTS' SUITABILITY FOR DIABETICS, UNDER PROPOSED FTC CONSENT ORDER

Estee Corp., a leading manufacturer of health-related special foods, has agreed not to advertise that its foods are useful or appropriate for diabetics' diets without adequate substantiation, the Federal Trade Commission announced today. Under the consent agreement, the company will also pay $25,000 in consumer redress in the form of research grants to the American Diabetes Association or the Juvenile Diabetes Foundation.

Estee produces a variety of dessert and snack foods, such as cookies and candies, sold chiefly to diabetics. The foods do not contain sucrose, or "table sugar," but are instead sweetened with fructose, sorbitol or high fructose corn syrup (HFCS).

The agreement settles charges Estee's magazine and label advertisements misled consumers by claiming the sweeteners in its foods "have been accepted by the [American Diabetes Association] and the [Food and Drug Administration] as being useful in the diets of diabetics on the advice of a physician." According to a complaint prepared as part of the agreement, neither the FDA nor the ADA has concluded that HFCS is useful for diabetics. For fructose and sorbitol, the FDA also has made no conclusions, while the ADA's conclusions are subject to significant qualifications.

According to the Commission, Estee lacked a reasonable basis for its unqualified statements that its fructose-sweetened and sorbitol-sweetened foods are appropriate for diabetics because these foods should not be eaten in more than limited amounts by diabetics and should not be eaten by out-of-control diabetics. Also, many of these foods are not useful for weight-control, an important consideration for many diabetics.

The complaint charged that Estee falsely advertised that its "fructose" foods are all sweetened with fructose, when in fact some are sweetened with HFCS. The Commission alleged Estee did not have a reasonable basis for its claims that these HFCS-sweetened foods are appropriate for diabetics and that HFCS has the same characteristics as fructose.

(More)

The complaint also charged that Estee's ads promoted the company's products as "dietetic" or reduced-calorie foods, when in fact many of the advertised foods did not contain significantly fewer calories than sucrose-sweetened products. Consequently, contrary to what the company's ads implied, these foods are not appropriate for weight loss or weight control diets.

In addition, according to the Commission, although Estee advertised that its products do not contain sugar, many of the foods are sweetened with fructose or high fructose corn syrup, both of which are sugars.

The proposed consent order announced today prohibits Estee from making misrepresentations about its products. The company must have reliable scientific evidence for claims that its foods affect blood sugar levels and for health-related claims that its foods are suitable for diabetics or hypoglycemics. In addition, when advertising that a food is recommended for diabetics or hypoglycemics, the company must disclose the identity of the endorser and any material limitations on that endorsement. Also, whenever a food is advertised as appropriate for diabetics, Estee's ads must state that food "is not a reduced calorie food" if that food is not defined as reduced calorie under FDA regulations.

Under the agreement, the company may not misrepresent the identity of a sweetener or the truthfulness of any endorsement, and may not claim that fructose and HFCS are not sugars. Estee also will not state that its foods are reduced in calories compared to other foods or are appropriate for weight-control unless such statements are true.

The company must pay the $25,000 for diabetes research within two years. Estee Corp. is located in Parsippany, N.J.

The consent agreement is scheduled to appear in the Federal Register Sept. 2. It will be subject to public comment for 60 days, until Nov. 1, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580. Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Mary Ann Miller, Office of Public Affairs,
202-523-1849

STAFF CONTACT: Robert C. Cheek, Bureau of Consumer Protection,
202-724-0726

(File No. 802-3165) (estee)

C-3144 final consent 10/1/8

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: July 17, 1984

WEIGHT-CONTROL CENTER PRESIDENT AGREES NOT TO MISREPRESENT EFFECTIVENESS OF "ACU-FORM" EAR MOLD DIET DEVICE

Thomas A. Dardas, president of Acu-Form Weight Control Centers Inc., has agreed not to claim that the "Acu-Form" ear mold or any other diet product is effective in helping consumers lose weight, unless he can substantiate those claims, under a Federal Trade Commission consent agreement issued today.

According to a complaint issued with the agreement, Dardas claimed in ads, "Now, with the Acu-Form ear mold, you can lose weight — quickly, safely, effortlessly! ... No restrictions on your lifestyle. The Acu-Form ear mold simply suppresses your appetite. You eat less and lose weight."

The Acu-Form ear mold was made of plastic and embedded with small steel pellets to stimulate the precise acupuncture points that modify appetite and eating habits, according to an Acu-Form brochure attached to the complaint. Customers were told to wear the ear mold and to press on the mold before eating. The pressure would allegedly stimulate the acupuncture points, making the wearer feel less hungry.

The complaint alleges Dardas did not have a reasonable basis to support his claims that the ear mold was an effective means of weight loss, could physiologically decrease or suppress the wearer's appetite, or would give the wearer permanent, life-time control over his or her weight.

Under the consent agreement Dardas must not claim that any weight loss or control product or service is effective or has any benefit, unless he has reliable and competent evidence that substantiates the claim.

The complaint also charges Dardas advertised a "100% money-back guarantee." However, there were "significant conditions attached" to what was represented as an unconditional money-back guarantee, according to the complaint. For example, to get a refund, consumers must have followed the "Acu-Form Diet Handbook" and must have returned to the place of business once a week for six weeks for counseling and weighing. Dardas agreed not to misrepresent the terms of any guarantee offered with any weight loss or control product or service.

The ear mold and counseling usually cost $300.

Acu-Form Weight Control Centers Inc. was not named in the complaint because it has filed for a liquidation bankruptcy under federal law.

(More)

The consent agreement is scheduled to appear in the Federal Register July 20. It will be subject to public comment for 60 days, until Sept. 18, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1892.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-523-1892

STAFF CONTACT: Elaine D. Kolish, Bureau of Consumer Protection,
202-523-3868

(File No. 832-3006)

(ACUFORM)

Biopractic is headquartered in Riegelsville, Pennsylvania. The firm sells Mineral Ice through drugstores, health-food stores and chiropractors. A 16-ounce container costs $14.95.

The proposed consent agreement is scheduled to appear in the Federal Register on Oct. 3. It will be subject to public comment for 60 days, until Dec. 3, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1848.

# # #

MEDIA CONTACT: Mario A. Baldessari, Office of Public Affairs,
202-523-1848

STAFF CONTACT: Bill Haynes, Bureau of Consumer Protection,
202-376-8720

(biopractic)

A + A Laboratories Permanent injunction (E.D. Va. 2/25/85)

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: August 7, 1984

FTC CHARGES COMPANY THAT ADVERTISES AND SELLS HAIR ANALYSES SERVICES DECEIVES AND MISLEADS CONSUMERS

FTC Asks Court to Order Consumer Redress

A Maryland-based hair analysis testing service is deceptive and potentially harmful to consumers' health, the Federal Trade Commission charged in a complaint filed yesterday in federal court. The Commission asked the court to grant preliminary and permanent injunctions against A & A Laboratories, prohibiting it from making false claims about the testing services.

The complaint also charges Trace Mineral Systems and New Age Nutritional Supplement Co., divisions of A & A, as well as Arthur Furman, Ethel Furman, his wife, and Alan Furman, their son, who together control the companies, with making false claims about hair analysis. The FTC also asked the court to freeze the assets of all the named parties to use for possible consumer redress.

The Commission charged that, contrary to their claims, hair analysis tests are grossly inaccurate and therefore worthless to consumers.

According to the FTC complaint, the defendants sell hair analysis services and vitamins, minerals and other dietary supplements. They advertise these services in national health-oriented magazines and at "holistic" health fairs around the country.

The defendants' ads offer hair analysis for $36.95. The ads say the laboratory will perform a scientific analysis of hair samples the consumer mails to the company. The ads further claim the lab will provide a detailed computer print-out, based on the hair analysis, that identifies the consumer's bodily mineral deficiencies and excesses, and will recommend specific vitamin, mineral and other dietary supplements. They also offer to sell consumers the "needed" dietary supplements.

According to the FTC complaint, the companies further represent that mineral deficiencies and excesses are associated with physical and mental disorders such as diabetes, arteriosclerosis, infertility and nervousness. The Commission alleged that the companies' recommendations to repeat the hair analysis and check the results of taking the dietary supplements every four months may lead some individuals to forego proper medical attention during that time, exposing them to substantial health risk or injury.

(More)

The FTC charged that the hair anaylsis tests do not provide a basis for determining the mineral levels in consumers' bodies. According to the Commission, even if the labs conducted the tests accurately, they would not provide a reliable basis for identifying an individual's bodily mineral deficiencies or excesses. The complaint also alleged that hair analysis does not provide a reliable basis for recommending dietary supplements.

FTC staff estimates that consumers now pay more than $25 million to 57 companies selling hair analysis services nationwide. FTC staff also estimates the companies' sales in 1983 totaled more than $500,000.

The FTC asked the court to prohibit the individuals and companies from claiming that:

- their hair analysis tests are accurate, unless they are;
- they can identify bodily mineral levels based on a multi-elemental analysis of an individual's hair; or
- they can recommend dietary supplements based on such a hair analysis.

In addition, the Commission asked the court to require the defendants to have a reasonable basis for any other representation relating to the accuracy or utility of hair analysis tests or the need for dietary supplements.

The laboratory represents that Arthur Furman supervises its services and refers to him as "Dr. Arthur F. Furman, Director of Medical Services." According to the FTC complaint, however, Furman is not a medical doctor.

The complaint also names other A & A divisions: Holistic Hair Analysis and Micro-Trace Minerals, in Alexandria, Va.; and Unique Concepts Advertising, the address of which is not known to FTC staff. The Furmans, A & A and New Age Nutritional Supplement are based in Ft. Washington, Md. Trace Mineral Systems has headquarters in Alexandria, Va.

The FTC filed the complaint in the U.S. District Court for the Eastern District of Virginia, Alexandria Division.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1892.

# # #

MEDIA CONTACT: Susan Tickner, Office of Public Affairs,
202-523-1892

STAFF CONTACT: Nancy B. Ramsey, Bureau of Consumer Protection,
202-523-0601

File No. 832 3243,
Civil Action No. 84-0803-A
[aa]

Figgie International Inc. D. 9166 ID 10/23/84

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: October 31, 1984

VANGUARD HEAT DETECTORS GIVE INSUFFICIENT WARNING OF FIRES, FTC JUDGE FINDS; DECISION UPHOLDS COMPLAINT CHARGES

Judge's Order Requires Affirmative Disclosures, Notification of Past Purchasers and Prohibits Misleading Claims

A Federal Trade Commission administrative law judge today upheld FTC complaint charges that Vanguard-brand heat detectors do not give sufficient warning to enable occupants to escape residential fires safely, contrary to their ads. The judge also held that promotional claims for the fire alarm systems, manufactured by Figgie International Inc.'s Interstate Engineering Division, are misleading and deceptive unless they warn that hazardous conditions, such as toxic fumes, can develop before the detector is activated.

A May 1983 FTC administrative complaint challenged Figgie's claims that Vanguard heat detectors provide the necessary warning to allow safe escape, and that Vanguard's combined heat and smoke detectors systems provide significantly greater fire warning protection than smoke detectors alone.

Figgie's fire alarm systems typically contain either five heat detectors and a single smoke detector or six heat detectors alone. The average system costs between $600 and $1,000. The company has headquarters in Richmond, Va., but sells nationwide.

Administrative Law Judge Montgomery K. Hyun found that Figgie knowingly used promotional material that made false performance claims for heat detectors and understated the importance of smoke detectors. According to the judge, the company did so by failing to give consumers the crucial information that hazardous levels of smoke, heat or carbon monoxide gas can develop and seriously impede a safe escape before heat detector alarms go off.

Hyun said the evidence shows that consumers rely on Figgie's express and implied claims when making purchasing decisions, but "that they will not be able to determine or find out for themselves, until it is too late for them, that hazardous conditions of smoke and gases will develop before a heat detector activates."

According to the judge, unless an appropriate order is issued, "consumers will continue to suffer substantial economic injury from the purchase of Vanguard heat detectors in the belief that they provide the necessary warning to allow a safe escape in most residential fires. Moreover, to the extent that heat detectors are purchased in lieu of smoke detectors in reliance [on Figgie's] misleading claims, a threat to life safety may be posed."

(More)

The judge said he was therefore issuing an order prohibiting Figgie from representing that:

- a heat detector will provide necessary warning without also saying that dangerous fumes may build up before the alarm goes off; or
- a combination heat/smoke detector system will provide significantly better protection unless the company also says such a system must include smoke detectors at specified locations.

The order also prohibits Figgie from misrepresenting standards for residential fire-safety devices or systems, such as those established by the National Fire Protection Association. It further states the company may not make performance claims unless they are substantiated by competent and reliable scientific evidence.

The order also contains affirmative disclosure requirements. Without a clear disclosure of heat detectors' serious limitations, Hyun said "any unqualified effectiveness claim for heat detectors will continue to mislead consumers into believing that heat detectors can be relied on to give adequate warning." He ruled that Figgie's print, film and tape ads, promotional material and sales literature used during in-home presentations must all contain the following disclosure: "CAUTION: In most residential fires dangerous levels of smoke, heat or carbon monoxide gas will build up before a heat detector alarm goes off."

When selling combination systems, the company must disclose that current fire safety standards require any residential smoke/heat detector combination system to include a smoke detector outside each sleeping area and on each additional level of the house.

In addition, the order requires the company to notify people who bought Vanguard heat detectors since Jan. 1, 1979, about the limitations of the devices and to inform them that combination systems must include a minimum number of smoke detectors.

According to the judge, this provision is "designed to ensure that the critical limitations are communicated to past purchasers who relied on [Vanguard's] misleading performance claims when they purchased heat detectors and continue to rely on such claims as true, thereby leaving themselves and their families with a false sense of safety in the event of a fire."

Although the judge upheld most complaint charges, he did not require certain disclosure language that FTC complaint counsel had requested. The disclosures would have required the following language: "Heat detectors will not help you get out of the house in time," or "heat detectors will not protect you from most fires."

The judge also rejected FTC complaint counsel's request that sales representatives obtain signed statements from purchasers acknowledging they have received necessary disclosures.

The parties have 10 days in which to appeal the decision; if they do not do so, the judge's decision and order may be issued as the Commission's decision and final order.

(More)

Copies of the initial decision are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1847.

# # #

MEDIA CONTACT: Linda L Singer, Office of Public Affairs, 202-523-1847

(FIGGIE)

[Docket No. 9166]

FTC NEWS NOTES
FEDERAL TRADE COMMISSION
Office of Public Affairs - Washington, D.C. 20580

Volume 37-83
June 3, 1983

VANGUARD HEAT DETECTORS DO NOT PROVIDE SUFFICIENT WARNING IN RESIDENTIAL FIRES, FTC CHARGES IN COMPLAINT AGAINST MAKER

Heat Detectors

The Federal Trade Commission has charged that Vanguard heat detectors do not provide sufficient warning in the event of residential fire to allow occupants time to escape safely, contrary to the claim made by the manufacturer, Figgie International Inc., in its promotional materials.

The FTC charged in its complaint that the company's claim is deceptive and said, "In nearly all residential fires, life-endangering conditions will occur prior to the activation of respondent's heat detectors."

Also, Figgie allegedly represented its "fire alarm systems combining heat detectors and smoke detectors provide significantly greater fire warning protection for occupants than smoke detectors alone." But the FTC charged this claim is deceptive because these systems are not significantly better than smoke detectors alone.

According to FTC staff, a typical Figgie residential fire alarm system, sold under the Vanguard trade name, consists of four to five heat detectors for every smoke detector, with the total system costing between $600 and $1000.

If the charges are upheld, the FTC has given notice it could seek to require Figgie to pay consumer refunds. The Commission could also:

- Prohibit Figgie from misrepresenting the performance or qualities of its heat detectors and fire alarm systems.
- Require Figgie to disclose to past and future purchasers that its heat detectors do not usually give adequate escape time and that its systems combining heat and smoke detectors do not offer much greater fire warning protection than smoke detectors alone.
- Require Figgie to take steps, including telling its distributors about the effectiveness and limitations of its heat detectors and fire alarm systems, so the distributors do not make any misrepresentations.

Figgie has headquarters in Richmond, Va.

The FTC's New York Regional Office investigated this case.

The Commission issues a complaint when it has "reason to believe" that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

(5.24.83)

(File No. 792 3046)

FTC documents mentioned in News Notes are available from the Public Reference Branch, Room 130, FTC, 6th and Pennsylvania Avenue N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

Descent Control Inc. C-3152
Final consent 4/29/85

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
[illegible]

FOR YOUR INFORMATION——June 12, 1985

The Federal Trade Commission has given final approval to the following consent agreements that it had provisionally accepted and placed on the public record for comments. They were all issued as final orders without modificiation.

- Associated Dry Goods Corp., one of the nation's leading retail companies. The consent agreement settles charges that the company failed to provide required Fair Credit Reporting Act notices to some consumers who were denied credit. The consent agreement was placed on the public record for comment Feb. 22 and issued M 7. (Docket No. C-3153)

- Descent Control Inc., manufacturer of safety devices for individuals working on or descending from tall buildings or heights. The consent agreement settles charges of false safety and performance claims. The consent agreement was placed on the public record for comment Feb. 5 and issued April 29. (Docket No. C-3152)

- P. Leiner Nutritional Products Corp., manufacturer of Octacol 4 capsules, which consist principally of wheat germ oil. The consent agreement settles charges of false and unsubstantiated advertising claims for the dietary supplement. The consent order was placed on the public record for comment Feb. 13 and issued May 3. (Docket No. 9173)

- Rush-Hampton Industries Inc., maker of the Ecologizer indoor air cleaner. The consent agreement settles charges of false, misleading and unsubstantiated ad claims that the system eliminated indoor air pollution. The consent order was placed on the public record for comment Feb. 5 and issued April 29. (Docket No. 9167)

- Young & Rubicam/Zemp Inc., advertising agency representing Rush-Hampton, makers of the Ecologizer air cleaner. The consent settles charges of false and unsubstantiated advertising claims for the product. The consent was placed on the public record for comment Feb. 5 and issued May 10. (Docket No. C-3154)

- Ward Corp., a Washington, D.C.-area home builder. The consent agreement settles a 1983 FTC complaint charging Ward with a substantial pattern of warranty violations in connection with its new homes. Under the consent order Ward will make repairs or pay homeowners for prior repairs that cost $500 or more to remedy. The consent order was placed on the public record for comment last Nov. 28 and issued April 5. (Docket No. 9168)

Descent Control Inc. D.C-3152 Final consent 4/29/85

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: January 31, 1985

MAKER OF SAFETY DEVICES MUST STOP MAKING FALSE CLAIMS, DISCLOSE SAFETY INFORMATION, UNDER FTC AGREEMENT

Descent Control Inc., which sells safety devices used by individuals working on or descending from tall buildings or other heights, must substantiate its advertising claims and tell users previously undisclosed safety information, under a Federal Trade Commission consent agreement announced today.

Descent Control manufactures and sells Sky Genie Descent Systems, which are devices composed of a nylon line attached to a shaft. A harness, boatswain chair, scaffold, waist belt or other items may be added to complete the system. Individuals who work at high elevations, such as window washers, construction workers and escape-and-rescue personnel, use the systems to stop falls and descend from heights at a controlled speed. The devices are also used to help individuals escape from high places during emergencies.

A complaint issued with the consent agreement charges that Descent Control made four false claims about its systems. It claimed that:

— the nylon lines used in the systems were long-lasting, when the lines are not safe and durable for long periods of time if used for rapid descents or to arrest a free fall;

— the systems could be preset for automatic, controlled descent, when the speed of descent actually depends upon manual control of the nylon line;

— the systems met all applicable Occupational Safety and Health Administration (OSHA) standards, when some parts of the systems do not meet applicable OSHA standards and some of the claimed OSHA standards do not exist; and

— the U.S. Army used the systems in the form they were offered for sale, when the Army actually uses them only after modifications that bring them up to its standards for escape and rescue.

Under terms of the consent agreement, Descent Control cannot make any of these or other safety or performance claims for the systems unless it can substantiate them.

The complaint also charges that Descent Control falsely claimed that its systems are safe and effective when used according to instructions, because the instructions omitted important information about the systems' safe use and proper maintenance.

(More)

Under terms of the consent agreement, Descent Control must disclose in its promotional material that consumers should:

- replace the device's nylon line after using the system twice for rapid descents (speeds greater than 15 feet per second);
- immediately replace the line after using the system to stop a free fall of two feet or more; and
- immediately replace the line after exposing the system to chemicals, such as hydrochloric acid, sulfuric acid and other substances to be listed in the revised operating instructions.

In the operating instructions, Descent Control must make all of these disclosures, as well as state that:

- the line should not be used as a safety line if it has ever been used as a utility line;
- the systems are not appropriate or safe for use in emergencies by individuals who are unfamiliar with the device's proper use; and
- a user's safety and speed of descent is dependent upon manual, not automatic, control.

The consent agreement also requires that Descent Control include revised technical bulletins and operating instructions in all of its systems already in the hands of its distributors. Further, it must place labels on these same systems, warning that the line may break under certain conditions and referring the user to the operating instructions for details.

Descent Control must mail notices containing the safety and use disclosures to all past purchasers of the systems and place ads detailing the disclosures in trade journals to notify past purchasers who may not receive direct notices.

Descent Control is based in Fort Smith, Ark.

The consent agreement is scheduled to appear in the Federal Register Feb. 5. It will be subject to public comment for 60 days, until April 6, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions.. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580. Copies of the consent agreement and complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638. News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1848.

# \# \#

MEDIA CONTACT: Mario A. Baldessari, Office of Public Affairs, 202-523-1848
STAFF CONTACT: Jeffrey M. Karp, Bureau of Consumer Protection, 202-523-3660

(File No. 842-3152) (descent)

Rush-Hampton Industries Inc. D. 9167
Final consent 4/29/85

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
[illegible]

FOR YOUR INFORMATION______June 12, 1985

The Federal Trade Commission has given final approval to the following consent agreements that it had provisionally accepted and placed on the public record for comments. They were all issued as final orders without modificiation.

- Associated Dry Goods Corp., one of the nation's leading retail companies. The consent agreement settles charges that the company failed to provide required Fair Credit Reporting Act notices to some consumers who were denied credit. The consent agreement was placed on the public record for comment Feb. 22 and issued M   7. (Docket No. C-3152)

- Descent Control Inc., manufacturer of safety devices for individuals working on or descending from tall buildings or heights. The consent agreement settles charges of false safety and performance claims. The consent agreement was placed on the public record for comment Feb. 5 and issued April 29. (Docket No. C-3152)

- P. Leiner Nutritional Products Corp., manufacturer of Octacol 4 capsules, which consist principally of wheat germ oil. The consent agreement settles charges of false and unsubstantiated advertising claims for the dietary supplement. The consent order was placed on the public record for comment Feb. 13 and issued May 3. (Docket No. 9173)

- Rush-Hampton Industries Inc., maker of the Ecologizer indoor air cleaner. The consent agreement settles charges of false, misleading and unsubstantiated ad claims that the system eliminated indoor air pollution. The consent order was placed on the public record for comment Feb. 5 and issued April 29. (Docket No. 9167)

- Young & Rubicam/Zemp Inc., advertising agency representing Rush-Hampton, makers of the Ecologizer air cleaner. The consent settles charges of false and unsubstantiated advertising claims for the product. The consent was placed on the public record for comment Feb. 5 and issued May 16. (Docket No. C-3154)

- Ward Corp., a Washington, D.C.-area home builder. The consent agreement settles a 1982 FTC complaint charging Ward with a substantial pattern of warranty violations in connection with its new homes. Under the consent order Ward will make repairs or pay homeowners for prior repairs that cost $500 or more to remedy. The consent order was placed on the public record for comment last Nov. 29 and issued April 5. (Docket No. 9160)

Rush-Hampton Industries, Inc. D. 9167
Final consent 4/29/85

FTC [illegible]

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: January 31, 1985

POLLENEX AND ECOLOGIZER AIR CLEANER MAKERS, AD AGENCY MUST NOT FALSELY CLAIM THEIR PRODUCTS CAN REMOVE AIR POLLUTANTS, UNDER FTC CONSENT AGREEMENTS

FTC Seeks Comments on Agreements with Associated Mills, Rush Hampton Industries Inc. and Young & Rubicam/Zemp Inc.

The manufacturers of two household indoor air cleaners, and the advertising agency for one of them, may not falsely represent the ability of their products to remove tobacco smoke or other pollutants from the air, under terms of consent agreements the Federal Trade Commission issued today for public comment.

The consent agreements settle separate 1983 administrative complaints the FTC issued against Associated Mills, maker of the Pollenex Pure Air "99" Air Cleaner/Deodorizer, and Rush-Hampton Industries Inc., marketer of the Ecologizer CA/90 Series 2000 Air Treatment System. The FTC charged the companies violated the law by making false, misleading and unsubstantiated advertising claims that their products could remove indoor air pollutants, including tobacco smoke, dust and pollen, and that the Ecologizer could also remove formaldehyde gas.

In a complaint released with a separate consent agreement with Young & Rubicam/Zemp Inc., Rush-Hampton's advertising agency, the FTC alleges the ad agency violated the law by making false claims about the Ecologizer.

Under the consent agreements, Rush-Hampton, Associated Mills and Young & Rubicam/Zemp Inc. have agreed not to misrepresent the ability of the Ecologizer or Pollenex air cleaners, or of any appliance or equipment, to clean household air.

In addition, the companies have agreed not to make any performance claims for air cleaning appliances or equipment unless they have competent and reliable tests substantiating the claims. In a separate document accompanying the agreement, Associated Mills indicated that, in developing substantiation, it will use tests conducted according to a protocol designed for the Association of Home Appliance Manufacturers.

The consent agreement with Associated Mills specifically prohibits the company from misrepresenting that the Pollenex Pure Air "99" Air Cleaner/Deodorizer Model 699 removes tobacco smoke, ragweed pollen or dust from the air people breathe. Under the consent agreement, the company must not falsely claim that the Model 699 effectively filters all the air in a 14- by-18-foot room in less than an hour.

(More)

The consent agreements with Rush-Hampton and Young and Rubicam/Zemp Inc. prohibit them from misrepresenting that the Ecologizer CA/90 Series 2000 Air Treatment System removes substantially all formaldehyde gas, tobacco smoke, household dust or pollen from the air. Under the consent, the companies must not falsely claim that the Series 2000 Air Treatment System effectively filters all the air in a 14-by-18-foot room in less than an hour.

According to FTC staff, in 1981 the relatively new indoor air cleaning industry as a whole sold more than 3.5 million units. In 1981 Rush-Hampton sold about 680,000 Ecologizers at a cost of $20 to $40, and Associated Mills sold more than 1.2 million Pure Air "99s" for about $35 each.

Rush-Hampton is located in Longwood, Fla., and Young & Rubicam/Zemp Inc. in St. Petersburg, Fla. Associated Mills is based in Chicago. In April 1984 Rush-Hampton sold its Ecologizer CA/90 air and water purification business to Talley Industries Inc., a Phoenix, Ariz., multi-industry company.

The consent agreements are scheduled to appear in the Federal Register Tuesday, Feb. 5. They will be subject to public comment for 60 days, until April 8, after which the Commission will decide whether to make them final.

Consent agreements are for settlement purposes only and do not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-523-1891

STAFF CONTACT: Judith Wilkenfeld, Bureau of Consumer Protection, 202-376-8648

FTC File Nos:
Rush-Hampton Inc. — 822 3171
Associated Mills — 822 3170

[RushAssoc]

FTC NEWS NOTES

WHITE HOUSE FELLOW OREN WHYCHE NAMED AS FTC SPECIAL ASSISTANT

White House Fellow

Federal Trade Commission Chairman James C. Miller III announced the appointment of Oren Elaine Whyche, a 1983 White House Fellow, as his Special Assistant. She is the first Fellow to serve with an independent regulatory agency. Her one-year appointment at the Commission will begin Sept. 1.

In addition to serving on the Chairman's staff, Whyche's chief responsibility will be to coordinate the FTC's outreach program, especially with small businesses.

White House Fellows are selected for their leadership, intellectual and professional abilities, as well as commitment to the community and the nation. In addition to Whyche's duties at the FTC, the Fellows program will offer her an education experience that includes meetings with a diverse group of public and private sector leaders.

Since 1981, Whyche has been Manager of Banking Relations for R. J. Reynolds Industries Inc. in Winston-Salem, N.C. From 1977 to 1981, she was with Morgan Guaranty Trust Co. in New York as an account manager. Whyche has also held positions with the Small Business Administration, Pan American World Airways Inc., Air Zaire, Ali-Foreman Productions Inc. and Callendar Consulting Engineers Inc.

She received a B.S. in Mathematics and French from Capital University in Columbus, Ohio, in 1971 and an M.B.A. in Finance from Columbia University in 1977.

(7.21.83)

# # #

FTC AMENDS PREMERGER NOTIFICATION RULES

premerger rules

The Federal Trade Commission has amended its premerger notification rules, which generally require large companies to file reports with the FTC and the Justice Department before commencing large mergers or acquisitions. These amendments to the Hart-Scott-Rodino Antitrust Improvements Act appeared in the Federal Register publication on July 29 and will become effective on Aug. 29.

Many of the changes are intended to clarify the rules and reduce the paperwork burden on companies filing the reports. The amendments include new exemptions for companies involved in specific types of transactions that now require reporting. Other changes are technical, such as correcting inadvertent omissions in the original rule language.

The Justice Department's Antitrust Division has formally concurred in the changes.

(7.20.83)

# # #

ECOLOGIZER INDOOR AIR CLEANERS DO NOT "GET RID OF" FORMALDEHYDE, TOBACCO SMOKE, POLLEN OR DUST AS ADS CLAIM, FTC CHARGES

Ecologizer air cleaners

The maker of the Ecologizer CA/90 indoor air cleaner has been falsely advertising that the device "gets rid of" such indoor air pollution as formaldehyde gas, tobacco smoke, dust and pollen, the Federal Trade Commission charged in a complaint.

Rush-Hampton Industries Inc. markets the household indoor air cleaner called the Ecologizer CA/90 Series 2000 Air Treatment System at a cost of $15 to $40. The relatively new indoor air cleaning industry as a whole sold more than six million units to consumers in 1982.

(continued on next page)

FTC NEWS NOTES

According to the complaint, Rush-Hampton ads were false and misleading. One radio ad claimed: "Look, besides tobacco smoke, dust, odors and pollen, the Ecologizer with CA/90 also gets rid of those harmful gases (formaldehyde and ammonia). It's the only one that does." A print ad claimed, "In a closed 16' x 14' room, the air will be completely recirculated, filtered and freshened every 33 minutes."

The FTC charged the device does not eliminate formaldehyde gas, tobacco smoke, pollen and dust from household air. In fact, the complaint continued, tests by both the company and an independent laboratory show the appliance at best can remove no more than five percent of formaldehyde gas and cannot eliminate pollen or dust from indoor air. The FTC also said independent tests determined the Ecologizer can remove at best only 15 percent of tobacco smoke from indoor air. And the FTC charged none of the tests uphold Rush-Hampton's air recirculation claim.

Also, Rush-Hampton allegedly falsely represented it had a reasonable basis for the ad claims. The FTC charged the companydid not conduct appropriate tests and did not use generally accepted procedures to apply the test results to advertised room conditions.

If an administrative law judge upholds the charges, the FTC has given notice it could issue an order prohibiting the company from falsely advertising the Ecologizer's effectiveness and the effectiveness of other indoor air cleaning products. The order may also require that future performance claims for similar products be supported by an adequate reasonable basis. The FTC could also prohibit Rush-Hampton from representing that any air cleaning appliance will perform under specific conditions, including household conditions, unless it relies on competent, appropriate scientific tests.

Rush-Hampton is located in Longwood, Fla.

(7.20.83) (File No. 822 3171)

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FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE $300

POSTAGE AND FEES PAID
U.S. FEDERAL
TRADE COMMISSION

THIRD CLASS
BULK RATE
Permit No. 081-000

P. Leiner Nutritional Products Corp. D. 9123
Final consent 9/3/85

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: February 8, 1985

MAKERS OF WHEAT GERM OIL CAPSULES MUST SUBSTANTIATE FITNESS CLAIMS, STOP MISREPRESENTING SCIENTIFIC STUDIES, UNDER PROPOSED CONSENT AGREEMENT

The makers of Octacol 4 wheat germ oil capsules cannot make unsupported claims that the product or its ingredients can improve physical fitness or performance and cannot misrepresent the results of scientific studies, under a proposed Federal Trade Commission consent agreement announced today.

The product, Octacol 4, is a capsule containing cold-processed wheat germ oil and four other ingredients — octacosanol, triacontanol, hexacosanol and tetracosanol — which the companies claimed were the "four sports stamina factors."

Octacol 4 is manufactured by P. Leiner Nutritional Products Corp. (formerly PLNP Holdings Inc.) and its wholly owned subsidiary, P. Leiner Nutritional Products Inc. of Delaware (formerly P. Leiner Nutritional Products Inc.).

The proposed consent agreement settles charges made in a 1984 FTC complaint concerning Octacol 4 ads that appeared in nationally distributed news, sports and trade magazines in 1982 and 1983.

The companies claimed in their ads that Octacol 4 contained "all four sports stamina factors" and "can help you get the most from your favorite sport — jogging, swimming, tennis, dancing or weight training." The complaint alleged that none of the ingredients in Octacol 4 improves a person's endurance, stamina, vigor, overall athletic performance or physical fitness.

The complaint also charged the companies falsely claimed that users of the product performed better after taking it, when they did not, and that scientific evidence supported their claims, when it did not. Ads said "long-term university studies and related research" proved that "athletes participating in these research studies were able to play and perform stronger, longer."

The complaint alleged the studies "were not conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results."

Under the proposed consent agreement, the companies cannot:

- claim that Octacol 4 or any other substantially similar product can improve vigor, stamina, endurance or any aspect of athletic performance or physical fitness;
- claim that octacosanol or the other three ingredients are in any way related to athletic endurance, performance or physical fitness;

(More)

- misrepresent the conclusions, data or results of scientific tests or resea. or

- claim their products provide any benefits related to improved or enhanced physical ability, unless they have reliable and competent data to back up such claims.

The consent agreement is scheduled to appear in the Federal Register Feb. 13. It will be subject to public comment for 60 days, until April 15, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the proposed consent agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1848.

# # #

MEDIA CONTACT:	Mario A. Baldessari, Office of Public Affairs, 202-523-1848
STAFF CONTACT:	Cheryl B. Anderson or Brinley H. Williams, Bureau of Consumer Protection, 202-376-8648 or 202-376-8720

(Docket No. 9173)

(octacol)

[illegible]

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: January 30, 1984

OCTACOL 4 CAPSULES DO NOT IMPROVE ATHLETIC PERFORMANCE, CONTRARY TO ADS, FTC CHARGES

Advertisements claiming the dietary supplement Octacol 4 "helps increase endurance, stamina and vigor" and contains four "sports stamina factors" that improve athletic performance are false and unsubstantiated, the Federal Trade Commission charged today in a complaint.

The FTC complaint named PLNP Holdings Inc. and its wholly owned subsidiary, P. Leiher Nutritional Products Inc., which is the manufacturer of the capsules. The pills principally consist of cold-processed wheat germ oil.

According to the complaint, Octacol 4 ads falsely claim that the product contains "all four sports stamina factors ... Triacontanol. Tetracosanol. Hexacosanol. And high-content octacosanol. Result? Octacol 4 can help you get the most from your favorite sport -- jogging, swimming, dancing, weight training, tennis or skiing."

The FTC charged the Octacol 4 ads falsely state that athletes perform better with the product. Also, the FTC charged none of the four ingredients makes it effective in improving athletic endurance, performance or physical fitness.

In addition, the complaint charges the ads falsely represent the company has a "reasonable basis consisting of competent and reliable evidence" to substantiate the claims. One ad stated, "Long-term university studies and related research" shows that "athletes participating in these research studies were able to play and perform stronger, longer."

However, the Commission said the studies mentioned in the ads "were not conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results." In addition, the Commission charges the studies did not provide a reasonable basis consisting of "competent and reliable scientific evidence" to back up the claims.

According to staff, the ads were published in national news and sports magazines from at least May 1982 through at least Oct. 1983 as well as in trade magazines. Staff say a 60-capsule bottle costs $7.00.

(More)

If the charges are upheld, the Commission could issue an order prohibiting PLNP Holdings and P. Leiner from representing that Octacol 4 can help consumers improve vigor, stamina, endurance, any aspect of athletic performance or any aspect of physical fitness.

The order could also:

-- Ban claims that the product's ingredients -- octacosanol, triacontanol, hexacosanol and tetracosanol -- are related in any way to athletic endurance or performance or physical fitness.

-- Prohibit any misrepresentations of any scientific data.

-- Require the companies to possess reliable and competent evidence if they make representations concerning any product's benefits for athletic performance, endurance,-hysical fitness, or any aspect of nutrition, or when comparing any product with a competing product regarding these characteristics.

-- Require the companies to keep all documents used to formulate ad claims covered by the order, including any documents that contradict the claims.

PLNP Holdings and P. Leiner have headquarters in Torrance, Calif.

Commissioner Michael Pertschuk supported the complaint but issued a separate statement. He expressed concern that the complaint only charges that the allegedly unsubstantiated claims were false, rather than including the "traditional" unfair and deceptive charge. He said this change may be "a step toward abandonment of unfairness as a basis for the advertising substantiation doctrine" and that would mark "a radical departure for the Commission."

The Commission issues a complaint when it has "reason to believe" that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

Copies of the complaint and proposed order are available from the FTC's Public Reference Branch, Room 130, Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Janet Bass, Office of Public Affairs, 202-523-1848
STAFF CONTACT: Andrew Sacks, Bureau of Consumer Protection, 202-376-8648
(Leiner) [File No. 832 3085]

Liquid Assets Default permanent injunctn. (C.D. Calif. 2/19/86)

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: May 6, 1985

ADS CLAIMING MOUTHWASH COUNTERACTS INTOXICATION ARE FALSE AND UNSUBSTANTIATED, FTC CHARGES

The Federal Trade Commission has asked a federal district court to issue a permanent injunction prohibiting advertising claims that a mouthwash, Breath Fresh 502, will sober persons who have consumed large amounts of alcohol and will allow them to pass breath analyzer tests.

The Commission charged the ads are false and deceptive because Breath Fresh 502, which contains hydrogen peroxide and flavoring, neither mitigates the effects of alcohol nor reduces measurable levels of alcohol. In addition, the Commission charged that William Jones, Breath Fresh 502's manufacturer, does not have a reasonable basis for making such claims. Jones conducts his business under the name Liquid Assets.

One Breath Fresh 502 ad cited by the Commission as an example claims: "Use like a mouthwash before drinking as a preventive, or after to save you embarrassment, time and money. Proven to help you beat any breath analyzer. Put yourself in control."

In announcing the action, Carol Crawford, director of the FTC's Bureau of Consumer Protection, stated: "Purchasers who rely on such claims may pose a serious threat, both to themselves and to others, particularly if they believe that the product will permit them to drive safely while intoxicated."

According to FTC staff, the mouthwash was sold through the mail and advertised in various national magazines. A four-ounce bottle of Breath Fresh 502 cost $14.95.

The Commission asked the court:

- to prohibit Jones from claiming that Breath Fresh 502 will counteract the intoxicating effects of alcohol consumption or reduce the measurable breath alcohol levels below those used to determine legal intoxication;
- to prohibit similar claims about counteracting the effects of alcohol consumption, unless the claims are substantiated by competent and reliable scientific evidence before they are made;
- to order Jones to notify those individuals who have bought the product since January 1983 that Breath Fresh will not reduce the intoxicating effects of alcohol, have any effect on breath alcohol level or help purchasers pass breath analyzer tests; and
- to order Jones to offer refunds to purchasers.

Liquid Assets is based in Lakewood, Calif.

(More)

The Commission filed its complaint for a permanent injunction in the United States District Court for the Central District of California.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1847.

# # #

MEDIA CONTACT: Linda L. Singer, Office of Public Affairs, 202-523-1847

STAFF CONTACT: Brinley Williams, Bureau of Consumer Protection, 202-376-8720

(LIQASSET)

Intra-Medic Formulations Inc.
Permanent injunction (S.D. Fla. 2/28/86)

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: August 14, 1985

COURT ISSUES TEMPORARY RESTRAINING ORDER AGAINST MAIL-ORDER COMPANIES FOR MISREPRESENTING DIET PRODUCTS AND BALDNESS "CURES"

FTC Alleges Ad Claims Were False

A federal court in Florida yesterday issued a temporary restraining order (TRO) halting four mail-order companies from misrepresenting their weight-control and baldness-cure products. The Federal Trade Commission charged the companies' claims for the products were false and deceptive.

The Commission also asked the court to issue a permanent injunction and to order the companies to pay refunds to consumers. The TRO and FTC complaint name Intra-Medic Formulations Inc. and its wholly owned subsidiaries, The Robertson-Taylor Co. Inc., W.G. Charles Co. Inc. and Connor-Freeman Laboratories Inc. Also named is Mitchell K. Friedlander, allegedly sole shareholder and president of Intra-Medic and a director of all of the companies.

The Commission charged the companies falsely and deceptively represented in ads for their Medi-Tec 90 baldness cure that:

— the product will cure baldness or cause new hair to grow;

— photographs in the ads depict the progressive regrowth of hair by a user of the product; and

— tests verify Medi-Tec 90 is effective in curing baldness and causing new hair to grow.

The Commission also charged that ads for the weight-control products Lipogene GH, Lipogene GHX, Intercal SX, Metabolite 2050 and Anorex CCK falsely and deceptively claimed that:

— the products allow people to lose weight without dieting or exercise; and

— scientific and medical evidence confirms the products are effective for enabling users to lose weight without dieting or exercise.

The companies had no reasonable basis for most of the weight-control or baldness-cure claims, the Commission charged.

The FTC filed the suit in the U.S. District Court for the Southern District of Florida. The companies are based, and Friedlander resides, in Ft. Lauderdale. The FTC's Atlanta Regional Office handled the investigation.

(More)

Weider Health and Fitness Inc. D. 9182 final consent
12/11/86

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 523-3830

FOR YOUR INFORMATION.........January 9, 1986

The Federal Trade Commission has given final approval to the following consent agreement that it had previously accepted and placed on the public record for comments:

-- Weider Health and Fitness Inc. The consent agreement settles charges that Weider misrepresented two nutrient supplements as substitutes for anabolic steroids. The agreement was placed on the public record Aug. 21 and issued Dec. 11. (D.9182)

A consent order is for settlement purposes only and does not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future violations. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the final order is available from the FTC's Public Reference Branch, Room 130, 6th & Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

A news release summarizing the complaint and consent agreement in the case was issued at the time of acceptance. News media copies of the release and final order is available upon request from the Office of Public Affairs, Room 496, same address; 202-523-1730.

# # #

MEDIA CONTACT: Darlene Harris, Office of Public Affairs, (202) 523-1730

Weider Health and Fitness, Inc. D. 9182

FTC

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: August 19, 1985

WEIDER TO PAY AT LEAST $400,000 IN CONSUMER REDRESS AND RESEARCH GRANTS UNDER FEDERAL TRADE COMMISSION AGREEMENT

Agrees Not To Misrepresent Products

Weider Health and Fitness Inc. and Joseph Weider have agreed to pay a minimum of $400,000 in refunds and research grants to settle charges they misrepresented two nutrient supplements, under a consent agreement the Federal Trade Commission announced today. Weider also agreed not to falsely claim that "Anabolic Mega-Pak" and "Dynamic Life Essence" are effective substitutes for anabolic steroids or help build muscles.

The agreement settles a July 1984 FTC complaint charging Weider misrepresented the supplements. Weider advertised and sold the supplements as substitutes for anabolic steroids, primarily to bodybuilders and weight trainers, who believe steroids increase muscularity and strength.

Weider agreed to make refunds to anyone who purchased Anabolic Mega-Pak and Dynamic Life Essence. If the total amount Weider refunds to consumers is less than $400,000, it will donate the difference to fund research on the relationship of nutrition to muscle development.

The company will notify customers of the refund opportunity and advertise it in Muscle and Fitness and Flex, two major bodybuilding magazines that Weider publishes through subsidiaries.

Weider also agreed not to claim that its products promote muscular development, produce human-growth hormone or are unique, unless it has competent and reliable scientific evidence. In addition, Weider agreed not to misrepresent any scientific test, research article, survey or other scientific opinion or data.

Joseph Weider and Weider Health and Fitness are both based in Woodland Hills, Calif. The agreement also names M.L.E. Holding Co. Ltd., which controls Weider Health and Fitness, and Ben Weider, president of M.L.E. and a former director of Weider Health and Fitness. M.L.E. and Ben Weider are based in Montreal.

The FTC's Chicago Regional Office handled the investigation.

(More)

The consent agreement is scheduled to appear in the Federal Register Aug. 21. It will be subject to public comment for 60 days, until Oct. 21, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 4[illegible], same address; 202-523-1848.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-523-1892
STAFF CONTACT:	Michael Sirota, Chicago Regional Office, 312-353-4423

(Docket No. 9182)

(Weider 2)

Weider Health and Fitness Inc.

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 523-3830

FOR YOUR INFORMATION..................January 11, 1985

The Federal Trade Commission has amended its complaint against Weider Health and Fitness Inc. and Joseph Weider, by adding M.L.E. Holding Co. Ltd. and Ben Weider as respondents.

The complaint, issued last July, alleged Weider Health and Fitness and Joseph Weider falsely represented that their "Anabolic Mega-Pak" and "Dynamic Life Essence" nutrient supplements were effective substitutes for anabolic steroids. Joseph Weider is president of Weider Health and Fitness.

The Commission added M.L.E. because it "has reason to believe" M.L.E. owns and controls Weider Health and Fitness and "has derived significant financial benefits from the allegedly deceptive acts or practices described in the complaint." Ben Weider, as president of M.L.E. and a member of the Board of Directors of Weider Health and Fitness, "has exercised the authority to formulate, direct and control the acts or practices of Weider Health and Fitness Inc., including the allegedly deceptive acts or practices described in the complaint," according to the Commission.

M.L.E. and Ben Weider are based in Montreal, and Weider Health and Fitness and Joseph Weider in Woodland Hills, Calif.

Copies of the Commission order amending the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1892.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-523-1892

(Docket No. 9182)

(WEIDER-ADD)

Weider Health and Fitness Inc. complaint

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: July 27, 1984

WEIDER FIRM FALSELY MISREPRESENTED PRODUCTS AS ANABOLIC STEROID SUBSTITUTES FOR BODYBUILDERS, FTC CHARGES IN ADMINISTRATIVE COMPLAINT

Weider Health and Fitness Inc. and its president, Joseph Weider, falsely represented that their "Anabolic Mega-Pak" and "Dynamic Life Essence" nutrient supplements were effective substitutes for anabolic steroids, the Federal Trade Commission charged in an administrative complaint today.

The complaint alleges these representations mislead consumers and induce them to purchase the nutrient supplements.

Ads for Weider's products claim the Anabolic Mega-Pak is "scientifically created," produces "faster-than-ever-before muscle growth," and is a "Natural Steroid Replacement Kit You Can Live With." Ads for Dynamic Life Essence say it is superior to "conventional protein sources to muscle up," is "unlike any other amino acid source in the world," and that "Life Essence Builds Bigger Muscles — Faster!"

Weider advertises the products primarily to bodybuilders and weight trainers, who believe anabolic steroids increase muscularity and strength. The international sports community has banned use of the steroids because they give users an unfair competitive advantage. In addition, steroids have many serious side effects, including liver cancer and hormonal changes in men and women.

Weider claims its products produce results similar to those of anabolic steroids without their dangerous side effects. The company advertises in two major bodybuilding magazines it publishes through subsidiaries, Muscle and Fitness and Flex.

The Anabolic Mega-Pak contains five pills or capsules containing various amino acids, minerals, vitamins and herbs. A 30-day supply costs $24.95. Dynamic Life Essence consists of capsules or powders of amino acids, which can cost up to $60 for a 30-day supply. Weider's ads suggest that the two products be taken together and claim that after several months of use the results will be similar to the results obtained from taking anabolic steroids.

According to the FTC complaint, Weider misrepresented that:

— a typical user would achieve greater muscular development over the course of a few months of a weight training program than a non-user of these products;

— a typical user would achieve at least the muscular development of a non-user, but in a shorter period of time;

(More)

- a typical user would achieve results equivalent to those results bodybuilders generally believe are achievable through use of anabolic steroids — rapid and substantial muscular development;
- the products would stimulate greater than normal production or release of human growth hormones, resulting in faster or greater muscular development;
- Dynamic Life Essence is unlike any other amino acid source in the world; and
- the Anabolic Mega-Pak was developed by a team of the world's most renowned nutritional biochemists, exercise physiologists and trainers.

The complaint alleged that Weider lacked substantiation for these claims.

The Commission issues a complaint when it has "reason to believe" that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon by an administrative law judge after a formal hearing.

If the judge finds Weider acted illegally, and the Commission affirms that decision, it can take any of several actions listed in a notice of contemplated relief accompanying the complaint. It could order Weider:

- not to make the claims listed in the complaint, unless they are true;
- not to make certain claims for any nutrient supplement or other food, unless there is competent and reliable evidence that substantiates the claims;
- not to misrepresent the purpose, content, reliability or conclusions of any scientific test, research article or any other scientific opinion or data; and
- to distribute a copy of the order to all mail-order customers of Anabolic Mega-Pak and Dynamic Life Essence, and to all distributors and retail outlets.

The Commission noted in the order of contemplated relief that it might also ask a court to order consumer redress or refunds.

Joseph Weider and Weider Health and Fitness are both based in Woodland Hills, Calif.

The investigation was conducted by the FTC's Chicago Regional Office.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638. News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1892.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-523-1892
STAFF CONTACT: Michael Sirota, Chicago Regional Office,
312-353-4423
(File No. 842 3187) (WEIDER)

Sunbeam Corp. D. C-3181 Final
Consent 2/11/86

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: November 25, 1985

SUNBEAM WILL NOT MISREPRESENT ABILITY OF ITS AIR CLEANERS TO ELIMINATE POLLUTANTS FROM HOMES AND OFFICES, ACCORDING TO FTC CONSENT AGREEMENT

The Federal Trade Commission charged today that Oster brand air cleaners do not effectively eliminate significant amounts of air pollutants and that ads for the air cleaners that appeared on television, radio and in print were false and misleading. In addition, the complaint charges that Sunbeam, the manufacturer of Oster air cleaners, also made unsubstantiated claims, despite the company's representations to the contrary.

Sunbeam's ads claimed that its Oster brand air cleaners effectively helped rid air of formaldehyde, gases from tobacco smoke and other gases that people breathe in homes and offices. Prices for the Oster air cleaner models 402 and 404 range from approximately $100 to $250.

Under a consent agreement settling these charges, Sunbeam has agreed not to misrepresent the ability of air cleaners to eliminate indoor pollutants. In addition, the company must have competent and reliable evidence for all future claims about any air cleaner's strength, capacity, speed of operation or other performance factors.

The FTC's San Francisco Regional Office conducted the investigation.

Sunbeam is headquartered in Pittsburgh, Penn.

The consent agreement is scheduled to appear in the Federal Register Nov. 29. It will be subject to public comment for 60 days, until Jan. 28, after which the Commission will decide whether to make it final. Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Linda I. Singer, Office of Public Affairs, 202-523-1847

STAFF CONTACT: Janet Grady, San Francisco Regional Office, 415-556-1270

(File No. 832-3259)
(Sunbeam)

North American Philips Corp. C-3180
(air filter) Final consent 2/10/86

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 523-3830

FOR YOUR INFORMATION.........March 27, 1986

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comments:

- Ashland Oil Inc. The consent agreement settles charges that the proposed merger involving Bass Brothers Enterprises Inc. and Ashland Chemical Co.'s Carbon Black Division is anticompetitive. Under the order, Ashland Oil Inc. must obtain FTC approval before selling any of its domestic carbon black plants to a major competitor. The agreement was placed on the public record Dec. 17, 1985, and issued March 12. (D. 9178)

- Rhode Island Board of Accountancy. The consent agreement settles charges that the Board restrained competition by prohibiting advertising and other forms of soliciting business and prevented accountants from providing services to the clients of other CPAs or PAs, unless requested to do so. Under the order, the board is prohibited from restricting any advertising, solicitation or encroachment by any person. The agreement was placed on the public record July 10, 1984, and issued on Feb. 25. (D. 9181)

- North American Philips Corp. The consent agreement settles charges that Norelco's Clean Air Machines do not effectively eliminate or help eliminate tobacco smoke, dust, pollen and other indoor pollutants and the irritation they cause. Under the order, Norelco agreed not to misrepresent the ability of air cleaners to eliminate indoor pollutants or the irritation they cause. The agreement was placed on the public record Nov. 29, 1985, and issued Feb. 10. (C-3180)

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future violations. Each violation of such an order may result in a civil penalty of up to $10,000.

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and final orders are available from the FTC's Public Reference Branch, Room 130, 6th & Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Darlene E. Harris, Office of Public Affairs, 202-523-1730

[secondstep]

(Air filter) North American Philips Corp. D.C-3180 Final Cease 2/10/

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: November 25, 1985

NORELCO AGREES NOT TO MISREPRESENT ABILITY OF ITS AIR CLEANERS TO ELIMINATE SMOKE AND OTHER IRRITANTS, FTC ANNOUNCES

The Federal Trade Commission charged today that Norelco's Clean Air Machines do not effectively eliminate or help eliminate tobacco smoke, dust, pollen and other indoor pollutants and the irritation they cause. According to the complaint, Norelco's table-top air cleaners do not circulate enough air through the filter to eliminate indoor air contaminants.

The Commission also charged that Norelco's use of a smoke chamber demonstration to show how the Clean Air Machines visibly remove smoke from the air was deceptive. The Commission claimed this demonstration did not represent how the air cleaner would work under normal household conditions. Norelco's air cleaners sell for $15 to $30 apiece.

Under a consent agreement settling these charges, Norelco agreed not to misrepresent the ability of air cleaners to eliminate or help eliminate indoor pollutants or the irritation they cause. The company also may not misrepresent the results of smoke chamber demonstrations or other tests, surveys or demonstrations of air cleaning appliances. In addition, the order requires Norelco to have competent and reliable evidence for all future claims about the air cleaners' performance.

Norelco is based in New York City.

The consent agreement is scheduled to appear in the Federal Register Nov. 29. It will be subject to public comment for 60 days, until Jan. 28, after which the Commission will decide whether to make it final. Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Linda L. Singer, Office of Public Affairs, 202-523-1847

STAFF CONTACT: Brinley H. Williams, Bureau of Consumer Protection, 202-376-8720

(File No. 842 3177)
(Norelco)

Roy Brog (Meadow Fresh) D. 9197 Final
consent 7/15/86

FTC

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: April 23, 1986

COMPANY OFFICER MAY NOT MAKE UNSUBSTANTIATED HEALTH CLAIMS ABOUT DRY MILK PRODUCT, UNDER FTC CONSENT AGREEMENT

Roy Brog, formerly chairman of the board of Meadow Fresh Farms Inc., a nationwide company that marketed a dry milk substitute, has agreed to have scientific evidence for any future health or nutritional claims he makes about the product, under a consent agreement with the Federal Trade Commission. The consent settles a 1985 FTC complaint that charged Brog with violating the law by not having substantiation for certain claims he made about the company's Meadow Fresh White.

The company sold the powdered, dairy-based milk substitute through a distributor network. The FTC charged in September 1985 that both Roy Brog and Larry Brog, formerly the company's chief executive officer, lacked a scientific basis for certain claims about Meadow Fresh. The FTC accepted a consent order that settled the charges against Larry Brog in December 1985.

According to the FTC, the Brogs did not have substantiation for their claims that Meadow Fresh had a shelf life of up to 10 years and that it would reduce the incidence of cardiovascular disease because it contained less xanthine oxidase, a milk enzyme, than whole milk. The consent agreement the Commission is announcing today requires Roy Brog not to make unsubstantiated claims about Meadow Fresh's shelf life or its ability to reduce cardiovascular disease. The consent also prohibits him from making any claims about health or nutritional benefits for Meadow Fresh or other food products unless he has reliable and competent scientific evidence substantiating his claims.

In addition, the consent prohibits Brog from excluding any distributors in computing "average" distributor earnings, unless he explains the exclusion. The FTC had charged the Brogs made false claims about the average earnings of distributors, substantially overstating the income distributors could reasonably expect to earn, by including in the statistics only those who had actually earned income.

In April 1985 a district court placed Meadow Fresh Farms into involuntary bankruptcy. Meadow Fresh and the Brogs are all based in Salt Lake City.

Commissioners Terry Calvani, Patricia P. Bailey and Mary L. Azcuenaga voted to accept the consent agreement; Chairman Daniel Oliver and Commissioner Andrew J. Strenio Jr. did not participate.

The consent agreement is scheduled to appear in the Federal Register April 28. It will be subject to public comment for 60 days, until June 27, after which the Commission will decide whether to make it final.

(More)

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-523-1891

STAFF CONTACT: Larry Hodapp, Bureau of Consumer Protection, 202-523-3860

FTC File No. D. 9197

[RoyBrog]

Brog, Roy
Brog, Larry (Meadow Fresh) D. 9197 Final
Consent 7/15/86

FTC

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: September 10, 1985

FTC CHARGES PRESIDENT OF COMPANY THAT MARKETED DRY MILK PRODUCT WITH MAKING UNSUBSTANTIATED CLAIMS ABOUT HIS PRODUCT

FTC Accepts Consent With Second Officer Settling Identical Charges

The Federal Trade Commission today issued an administrative complaint charging Roy Brog, president of Meadow Fresh Farms Inc., a nationwide company that marketed a dry milk substitute, with making unsubstantiated claims about the product's shelf life and its ability to reduce cardiovascular disease.

At the same time, the FTC accepted a consent agreement with Larry Brog, formerly chief executive officer of Meadow Fresh, settling Commission charges that he engaged in the same law violations. The consent requires Larry Brog to have scientific evidence for any claims he makes about Meadow Fresh or other food products in the future.

The company sold its product, Meadow Fresh White, a powdered, dairy-based milk substitute, through a distributor network. The FTC charged that the Brogs lacked a scientific basis for their claims that Meadow Fresh White had a shelf life of up to 10 years and that it would reduce the incidence of cardiovascular disease because it contained less xanthine oxidase, a milk enzyme, than does whole milk.

The FTC also charged the Brogs made false claims about the average earnings of distributors by substantially overstating the income they could reasonably expect to earn.

The Commission issues a complaint when it has reason to believe that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

The consent agreement with Larry Brog prohibits him from making any claims about health benefits or expected shelf life for Meadow Fresh or other food products unless he has reliable and competent scientific evidence substantiating his claims. The consent also prohibits Brog from excluding some distributors in computing "average" distributor earnings unless he explains the exclusion.

In April, a district court placed Meadow Fresh Farms into involuntary bankruptcy. Meadow Fresh and the Brogs are all based in Salt Lake City.

The consent agreement with Larry Brog is scheduled to appear in the Federal Register Sept. 17. It will be subject to public comment for 60 days, until Nov. 18, after which the Commission will decide whether to make it final.

(More)

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the administrative complaint against Roy Brog, the consent agreement with Larry Brog and the accompanying complaint and an analysis of the consent agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-523-1891

STAFF CONTACT: Larry Hodapp, Bureau of Consumer Protection, 202-523-3860

FTC File No. 832 3042

[meadow]

Figgie International, Inc. D. 9166 Commission Decision 4/10/86

FTC news

Federal Trade Commission Washington, D.C. 20580

Appeal filed 4th Cir. 6/16/86

Aff'd (4th Cir. 4/21/87)

FOR IMMEDIATE RELEASE: April 23, 1986

FTC RULES VANGUARD HEAT DETECTORS DO NOT PROVIDE NECESSARY WARNING TO ALLOW ESCAPE FROM MOST FIRES; ORDERS COMPANY NOT TO MAKE DECEPTIVE CLAIMS

The Federal Trade Commission today ruled that Vanguard heat detectors do not provide consumers with the necessary warning to escape from most residential fires, saying "heat detectors often provide no advance warning." The FTC said claims that Vanguard heat detectors give "immediate early warning" are deceptive and ordered the manufacturer, Figgie International Inc., not to misrepresent the devices' ability to provide such warning.

The Commission opinion, written by Commissioner Mary L. Azcuenaga, said that evidence from tests conducted by firefighting organizations and government agencies showed that "smoke detectors provide significantly earlier warning of potentially dangerous conditions resulting from a residential fire than do heat detectors."

The Commission ordered Figgie to provide notification that smoke detectors give earlier warning than heat detectors in nearly all residential fires to past purchasers of its heat detectors. Figgie must also disclose that fact in any future promotional materials that make claims about the residential fire protection provided by heat detectors.

The Commission said that Figgie's claims that heat detectors provide significant additional protection when installed in kitchens, garages and other areas where smoke detectors would not function properly "are not necessarily deceptive." While experts testified that few fatal fires start in these parts of the house, the Commission concluded that the extra protection afforded by heat detectors in these areas could be considered significant by consumers. However, such claims must be substantiated, must not exaggerate the extent of the additional protection and must disclose any necessary qualifying information, according to the opinion.

The Commission also ruled that claims that Vanguard heat detectors are more reliable than smoke detectors may not be deceptive. Unlike smoke detectors, heat detectors do not run on electricity or batteries, and do not require occasional cleaning. However, the Commission said that claims concerning the extra protection provided by the greater mechanical reliability must be truthful and substantiated.

Figgie's claims that Vanguard heat detectors respond more quickly than smoke detectors to hot, flaming fires are false, the Commission ruled. It cited tests that showed that smoke detectors give earlier warning of both smoky, smoldering fires and flaming fires.

The Commission ordered Figgie not to claim that heat detectors provide the necessary warning to allow safe escape from most residential fires and also not to claim that fire alarm systems combining heat and smoke detectors provide significantly greater protection than smoke detectors alone for hot, flaming fires.

(More)

In addition, Figgie cannot misrepresent the performance characteristics of any heat or smoke detectors, or of any system containing both. The order also prohibits Figgie from misrepresenting any standard or recommendation established by the National Fire Protection Association or any other group concerning fire warning systems.

Figgie is required to inform all of its dealers of the Commission order and not to do business with any dealer who fails to obey the order.

The Commission voted unanimously to issue the order. However, Commissioner Patricia P. Bailey dissented from the part of the opinion that failed to find deceptive Figgie's claims that its heat detectors provide "significantly greater" protection because they can be placed in kitchens and garages, and because they are mechanically reliable. In her view, the evidence demonstrates that Figgie's heat detectors, alone or in combination with smoke detectors, "do not provide 'significantly greater' fire warning protection for occupants than smoke detectors alone, and Figgie should have been told directly in the order not to make that claim again."

Figgie is based in Richmond, Va., and sells its systems nationwide. From January 1, 1981, to May 31, 1983, its revenues from sales of Vanguard heat detectors totalled $2,354,000. Figgie's fire alarm systems typically contain either five heat detectors and a single smoke detector or six heat detectors alone. The average system costs between $600 and $1,000.

Copies of the Commission opinion and order are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-523-1848

(Docket No. 9166)

(Figgie)

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: August 6, 1986

ADMINISTRATIVE LAW JUDGE RULES R. J. REYNOLDS SMOKING AND HEALTH AD IS NONCOMMERCIAL SPEECH PROTECTED BY FIRST AMENDMENT; GRANTS COMPANY'S REQUEST TO DISMISS FTC COMPLAINT

A Federal Trade Commission administrative law judge has ruled that an R. J. Reynolds Tobacco Co. statement on smoking and health, challenged by the FTC as a commercial cigarette ad, is an editorial and therefore is not subject to the Commission's jurisdiction. The judge issued an order granting the company's request to dismiss the complaint and stayed the proceedings pending a Commission ruling.

Judge Montgomery K. Hyun's decision dismisses a June 16 FTC complaint charging that R. J. Reynolds' statement, titled "Of Cigarettes and Science," misrepresented the purpose and results of a major government-funded study. The cigarette statement ran from March to June 1985 in leading newspapers and magazines, including the Washington Post, the New York Times, Newsweek, and Time. It discussed the Multiple Risk Factor Intervention Trial, referred to as MR FIT, which was funded by the National Heart, Lung, and Blood Instutute of the National Institutes of Health.

The complaint charged that the cigarette statement made three claims about the MR FIT study that were false or misleading and that the ad was deceptive because it failed to disclose certain information about the study's findings.

On June 26, R. J. Reynolds made a motion to dismiss the FTC complaint, and on July 22 Judge Hyun heard oral arguments on the motion by the FTC staff and the company.

According to Judge Hyun, the sole issue in this case is whether Reynolds' cigarette statement may properly be classified as commercial speech, which enjoys limited First Amendment protection but is nevertheless subject to government regulation, or noncommercial speech, which is fully protected by the First Amendment and lies beyond the power of government regulation. The judge concluded that "controlling case law compels the conclusion that the ad in this case is noncommercial speech and as such lies beyond the subject matter jurisdiction" of the FTC.

Judge Hyun concluded that the "ad is an editorial ad expressing Reynolds' point of view on the issue of smoking and health." He stated that the ad does not give any brand names or prices, discuss desirable attributes of a product, show where the product may be purchased, or contain any express promotional language. Therefore, the judge rejected the FTC staff's argument that, because "the ad was intended and designed to persuade smokers not to quit," the ad was commercial speech.

Judge Hyun wrote, "We think the language of the ad is uncomplicated and the ad will be easily understood by any reasonable reader as an op-ed piece, not a cigarette ad. Once so perceived by the reader, he or she will expect to read in the ad an expression of opinion, an advocacy of a certain point of view, or even hyperbole by someone who may have an ax to grind."

(More)

According to Judge Hyun, the ad may not be entirely accurate or complete and some of what it may imply may be self-serving. However, he concluded, "editorial or noncommercial speech, such as the Reynolds' ad, does not lose the full protection of the First Amendment simply because it contains inaccurate or incomplete information, or some language which may arguably be construed or misconstrued to imply a promotional message."

The FTC staff may appeal the decision to the Commission.

R. J. Reynolds Tobacco Co Inc., a subsidiary of RJR Nabisco Inc., is one of the major cigarette manufacturers in the United States. It manufactures more than 20 brands of cigarettes and accounts for about one-third of the U.S. cigarette market. R. J. Reynolds is based in Winston-Salem, N.C.

Copies of the judge's decision are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-523-1891

FTC File No. D. 9206

[RJRDec]

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: June 16, 1986

R. J. REYNOLDS AD ON SMOKING AND HEALTH IS MISLEADING, FTC CHARGES IN COMPLAINT

The Federal Trade Commission charged in an administrative complaint issued today that R. J. Reynolds Tobacco Co. Inc. misrepresented the purpose and results of a major government-funded study in an advertisement.

The ad, titled "Of Cigarettes and Science," ran from March to June 1985 in leading newspapers and magazines, including the Washington Post, the New York Times, Newsweek, and Time.

According to the complaint, the ad made three claims about the study that the FTC alleges are false or misleading:

- that it was designed and performed to test whether cigarette smoking causes heart disease;
- that it provides credible scientific evidence that smoking is not as hazardous as the public or the reader has been led to believe; and
- that it tends to refute the theory that smoking causes heart disease.

In addition, according to the complaint, R. J. Reynolds failed to disclose in the ad that men in the study who quit smoking had a significantly lower rate of death from heart disease than men who continued to smoke or that the study's results are consistent with previous studies showing that those who quit smoking have a substantial decrease in death from heart disease. The complaint charged that in light of the claims made in the ad, the omission of this information made the ad deceptive.

The study discussed in the ad is the Multiple Risk Factor Intervention Trial, referred to as MR FIT, which was funded by the National Heart, Lung and Blood Institute of the National Institutes of Health.

The Commission issues a complaint when it has reason to believe that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

If the Commission's allegations are upheld, R. J. Reynolds could be prohibited from misrepresenting in ads discussing cigarette smoking and health the purpose or results of the MR FIT study or any other scientific tests or studies. The company could also be required to disclose the omitted information about death from heart disease in ads that discuss results of the MR FIT study and question the relationship between smoking and smokers' risk of heart disease.

(More)

The vote to issue the complaint was 4-1, with Chairman Daniel Oliver dissenting. Chairman Oliver said in a separate statement, "I believe that, as a matter of public policy, it is valuable for the public to hear all sides of an issue, and I am concerned about taking any action that may inhibit free expression of views that might not be popular to government regulators." Commissioner Andrew J. Strenio Jr. said he supports the issuance of this complaint, but dissents from the inclusion of paragraph seven.

R. J. Reynolds Tobacco Co. Inc., a subsidiary of RJR Nabisco Inc., is one of the major cigarette manufacturers in the United States. It manufactures more than 20 brands of cigarettes and accounts for about one-third of the U.S. cigarette market. R. J. Reynolds is based in Winston-Salem, N.C.

Copies of the complaint and proposed order are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-523-1891

STAFF CONTACTS: James H. Skiles, Bureau of Consumer Protection, 202-376-8548

FTC File No. 852 3143

[RJReynolds]

Buckingham Productions, Inc. D. 9194
final consent 7/30/87

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
[illegible]

FOR YOUR INFORMATION____________August 19, 1987

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

— First American Title Insurance Co. The consent order settles FTC charges that the company unlawfully fixed prices on title search, examination and settlement services through its participation in rating bureaus in Arizona, Connecticut, Idaho, Montana, Ohio, and Wisconsin. Under the consent order, First American agreed not to set those rates through a rating bureau unless the state permits and supervises that conduct.

A consent agreement was placed on the public record May 11 and the consent order issued July 30. (Docket No. 9190)

— Buckingham Productions Inc. The consent order settles 1985 FTC charges that Buckingham, several related companies, and individuals who sold weight reduction programs made false, misleading, and unsubstantiated weight loss claims for their mail-order programs and products. Under the consent order, the companies and individuals are prohibited from making such claims in the future.

The FTC issued the administrative complaint in June 1985. The consent agreement was placed on the public record Aug. 15, 1986, and the consent order issued July 30, 1987. (Docket No. 9194)

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

(SecStpa)

Buckingham Productions, Inc. D. 9194
final consent agreement 7/28/87

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: August 14, 1986

MARKETERS OF "ROTATION DIET" BARRED FROM MAKING FALSE OR MISLEADING CLAIMS, UNDER FTC CONSENT AGREEMENT

The Federal Trade Commission today announced that the marketers of the "Rotation Diet" and several related weight-reduction plans have signed a provisional consent agreement, settling charges that they made false, misleading, and unsubstantiated claims in advertising for their mail-order programs and products.

In June 1985 the FTC issued an administrative complaint against Buckingham Productions Inc., several related companies, and individuals who sold weight reduction programs under the following names: the Rotation Diet, the 'No Frills' Rotation Diet, the Freedom Diet, the Freedom Plus' Diet, and the Rotation-Freedom Diet.

According to the Commission's staff, past FTC cases have concluded that dieters will lose weight and maintain weight loss only if they reduce their total caloric intake over a period of time. The Commission challenged as false Buckingham's claims that dieters could eat virtually unlimited quantities of any food they wished for four days each week and still lose weight if, on the other days, they followed a severely restricted low-calorie diet and took the company's vitamin supplements and wafers. The Commission also challenged claims that the usual monthly weight loss for women was 8 - 20 pounds and 12 - 25 pounds for men. According to the complaint, Buckingham lacked substantiation for these statements and for claims that the diets were proven safe. In addition, the Commission alleged that some testimonials Buckingham used in ads were misleading, because it was not disclosed that they were given by Buckingham employees.

Under the proposed agreement, Buckingham is prohibited from claiming that consumers can eat as much food as they want and still lose weight without disclosing that weight loss depends on the reduction of total caloric intake. In addition, Buckingham may not claim that consumers have lost any specific amount of weight, that any product helps keep food from turning to fat, or that it stops hunger or prevents fatigue, unless such claims are true. Buckingham also must have competent and reliable evidence to substantiate usual, average, or range of weight-loss claims and representations about the safety of its products.

The agreement also restricts Buckingham's use of endorsements and requires that it disclose any relationship between an endorser and the company, if that relationship might significantly affect the endorser's credibility.

As part of the agreement, the Commission added a corporate respondent, Health and Diet Corp. Inc., and dropped charges against four individuals orginally named in the complaint.

NOTE TO EDITORS: Buckingham Production's "Rotation Diet" is not related to and should not be confused with Dr. Martin Katahn's currently available "Rotation Diet."

(More)

In addition to Buckingham Productions Inc., which does business as the Rotation Diet Center, the complaint and consent name the following companies: Furlong-Elliot Corp.; Freedom Center Inc.; Plaza Business Services Inc.; N.F. Rotation Inc.; and Rotation-Freedom Diet Inc. All the companies are located in Furlong, Pa. The complaint and consent also name Howard Elliot, an officer of the corporations. The companies and Mr. Elliot are no longer promoting mail-order diets.

The consent agreement is scheduled to appear in the Federal Register Aug. 15. It will be subject to public comment for 60 days, until Oct.14, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Linda I. Singer, Office of Public Affairs, 202-523-1585

STAFF CONTACT: Michael Dershowitz, Bureau of Consumer Protection, 202-376-8720

(File No. D 9194)
(buckingham)

Buckingham Productions, Inc. D. 9194
Complaint

FTC

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: July 9, 1985

FTC CHARGES ADVERTISEMENTS FOR SEVERAL RELATED DIET PROGRAMS CONTAINED MISLEADING CLAIMS, ENDORSEMENTS AND TESTIMONIALS

Expert Endorser Settles Related FTC Charges He Made False and Unsubstantiated Claims

The marketers of the "Rotation Diet" and several related weight-reduction plans made false, misleading and unsubstantiated claims in advertisements for their mail-order programs and products, the Federal Trade Commission charged in a complaint announced today. Dr. Barry Bricklin, an expert in the psychology of dieting, signed a consent agreement settling related Commission charges that he provided false and misleading endorsements for the diet plans.

Buckingham Productions Inc., five related companies and several individuals sold weight-reduction programs under several names: the "Rotation Diet," the " 'No Frills' Rotation Diet," the "Freedom Diet," the "Freedom Plus Diet" and the "Rotation-Freedom Diet."

Advertisements for the diet plans claimed that dieters could eat virtually unlimited quantities of any food they wished for four out of seven days each week and still lose weight if, for the other three days, they followed a severely restricted low-calorie diet along with the company's vitamin supplements and wafers. Under the plans, the dieter alternated (or "rotated") between "free" days (no caloric restrictions) and "balance" days (calorically controlled).

Past Commission cases have established that people on a diet will lose weight and maintain weight loss only if they reduce their total caloric intake over a period of time. Ads for these diets expressly claimed that a range of weight loss per month — eight to 20 pounds for women and 12 to 25 pounds for men — was usual. According to the complaint, Buckingham did not have substantiation for these claims. The ads also claimed the diets were proven safe and could not harm dieters. The complaint charged these claims were similarly unsubstantiated.

The Commission alleged that testimonials by users of the Rotation Diet were not genuine. The Commission also charged that the photographs accompanying other testimonials were in fact photographs of Buckingham employees. The Commission charged that failure to disclose the connection between Buckingham and the photographed individuals was misleading, because reasonable consumers would not expect such a connection, and such disclosure would have affected the credibility of the testimonials.

In addition, the Commission charged that Dr. Barry Bricklin, a psychologist and expert in the psychological aspects of dieting, represented that he used his expertise to test and evaluate the products in the same way similarly qualified experts would normally do. The Commission charged he did not have such substantiation. In addition, the complaint alleged that based on his expertise, Dr. Bricklin knew or should have known that the claims in his endorsements were false and misleading.

(More)

[illegible] representing, in the future, that consumers [illegible] as much food as they want and still lose weight without also giving the specified disclosures about weight reduction. Dr. Bricklin is also prohibited from making claims about "usual" or "average" weight loss, or about the efficacy or performance of weight reduction or weight control products or programs, unless he relies on competent and reliable surveys or other scientific evidence for substantiation, as defined in the agreement.

The ads for the diets appeared in national magazines including Family Circle, Woman's Day, T.V. Guide, Redbook, Family Weekly and Playgirl, as well as The Chicago Tribune, The National Enquirer, The New York Daily News, Newsday and other major newspapers. The claims also appeared in television and radio ads and direct-mail brochures.

In addition to Buckingham Productions Inc., which does business as the Rotation Diet Center, the complaint names the following companies: Furlong-Elliot Corp.; Freedom Center Inc.; Plaza Business Services Inc.; N.F. Rotation Inc.; and Rotation-Freedom Diet Inc. Buckingham Productions is located in Doylestown, Pa. The other companies are located in Furlong, Pa. The complaint also names the following individuals who allegedly directed and controlled the practices of the various companies: Howard Elliot; Gail Elliot; Judy Ruthrauff; Dorothy Woolslager; and Benito Ventresca.

The Commission voted unanimously to issue the complaint, with Commissioners Mary Azcuenaga and Patricia P. Bailey dissenting as to the inclusion of Dr. Bricklin. The Commission voted 3-2 to accept the consent agreement with Dr. Bricklin. Commissioners Azcuenaga and Bailey dissented from the decision to accept an agreement that places Dr. Bricklin under an order to cease and desist, explaining that they did not have "reason to believe Dr. Bricklin should be charged with violations of Sections 5 and 12 of the FTC Act."

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

The consent agreement is scheduled to appear in the Federal Register shortly. It will be subject to public comment for 60 days, after which the Commission will decide whether to make it final. Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the complaints, consent agreement and analysis of the agreement to aid public comment are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638. News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1847.

# # #

MEDIA CONTACT:Linda L. Singer, Office of Public Affairs, 202-523-1847

STAFF CONTACT:Michael Dershowitz, Bureau of Consumer Protection, 202-376-8720

(DIET)

Viobin Corp. D.C-3204 Final Consent
12/17/86

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: October 9, 1986

VIOBIN AND A.H. ROBINS MAY NOT MAKE FALSE OR UNSUBSTANTIATED CLAIMS ABOUT EFFECTS OF WHEAT GERM OIL PRODUCTS ON PHYSICAL FITNESS, UNDER FTC CONSENT AGREEMENT

The Federal Trade Commission today charged that Viobin Corp. made false and unsubstantiated claims about its wheat germ oil products. Viobin and its parent company, A.H. Robins Co. Inc., agreed to settle the charges.

Under a proposed consent agreement, Viobin must inform consumers that the benefits claimed in its long-running advertising campaign are not supported by scientific evidence; and both Viobin and A.H. Robins are prohibited from misrepresenting the ability of their wheat germ oil products to improve physical fitness or performance.

Viobin claimed that its wheat germ oil products, sold under the brand names Viobin Wheat Germ Oil (liquid), Prometabs (tablets), and Prometol (capsules), would improve consumers' physical fitness and performance by increasing endurance, stamina, total body reaction time, and vigor, as well as helping to overcome fatigue. Viobin made claims such as: "More than 18 years of university research show positive evidence that Viobin Wheat Germ Oil can help athletes increase stamina and endurance plus help them overcome fatigue more quickly. These benefits are achieved separately and apart from the effects of physical training."

In a complaint accompanying the agreement, the Commission charged that Viobin's claims were false and that Viobin's products and its active ingredient, octacosanol, are not effective for their advertised purposes. The Commission also charged that Viobin lacked a reasonable basis for its claims.

Under the proposed order, Viobin and A.H. Robins are prohibited from representing that their wheat germ oil products can help consumers improve endurance, stamina, vigor, or any aspect of athletic fitness, or that octacosanol is in any way related to body reaction time, oxygen uptake, oxygen debt, or athletic performance.

Viobin is also prohibited from misrepresenting the results of any scientific test or research about any product intended for personal or household use. A similar prohibition extends to A.H. Robins' claims for any wheat germ oil product. Both companies are prohibited from making claims concerning benefits of any personal or household product on athletic performance or endurance unless they are substantiated by reliable and competent evidence.

In addition, Viobin must state, in any ad it runs within the next year, that "earlier studies of the effects of wheat germ oil and octacosanol on endurance, stamina, and vigor do not meet the criteria of modern testing," and that the company no longer claims that such products will improve endurance, stamina, and vigor. Within six months after the order becomes final, Viobin must place an ad including this disclosure in each of the publications that carried its ads in 1985. According to FTC staff, the purpose of this provision is to remedy false impressions created by Viobin's false and deceptive advertising for its wheat germ oil products.

(more)

Viobin is based in Monticello, Ill., and is a wholly owned subsidiary of A.H. Robins of Richmond, Va.

The consent agreement is scheduled to appear in the Federal Register Oct. 10. It will be subject to public comment for 60 days, until Dec. 9, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Linda I. Singer, Office of Public Affairs, 202-326-2178

STAFF CONTACT: Brinley Williams, Bureau of Consumer Protection, 202-376-8684

(File No. 852 3158)
(VIOBIN)

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 326-2180

FOR YOUR INFORMATION..............February 9, 1987

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

- Cosmo Communications Corp. The consent agreement settles charges that the company misrepresented the capabilities of its touch-pulse phones. The agreement was placed on the public record Sept. 22 and issued Dec. 12. The Commission vote to accept the consent agreement in final was 3-2, with Chairman Daniel Oliver and Commissioner Mary L. Azcuenaga dissenting. (Docket No. C-3202)

- Viobin Corp. The consent agreement settles charges that Viobin, a wholly owned subsidiary of A.H. Robins Corp., made false and unsubstantiated claims about its wheat germ oil products. The agreement was placed on the public record Oct. 9 and issued Dec. 17. (Docket No. C-3204)

- International Masters Publishers Inc. The consent agreement settles charges that the mail-order seller of "My Great Recipes" did not promptly honor membership cancellation requests or promptly credit the accounts of consumers who returned recipe cards. The agreement was placed on the public record Nov. 4 and issued Jan. 14. (Docket No. C-3205)

- Solar Age Industries Inc. The consent agreement settles charges that the company falsely claimed that its solar energy heater could reduce significantly residential heating fuel consumption and would pay for itself in a few years. The agreement was placed on the public record Nov. 4 and issued Jan. 28. (Docket No. C-3206)

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-326-2179

(SecStp)

Aquanautics Corp. C-5207
Final consent 2/17/87

OFFICE OF PUBLIC AFFAIRS
[illegible]

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

FOR YOUR INFORMATION................March 18, 1987

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

- Aquanautics Corp. The consent agreement settles charges that the company falsely claimed its marine survival suit would keep users afloat for long periods of time and would decrease the likelihood of drowning. The agreement was placed on the public record Nov. 21 and issued Feb. 17. (Docket No. C-3207)
- J.C. Penney Co., Inc. The consent agreement settles charges that Penney filed debt-collection cases in courts far from where customers lived. The agreement was placed on the public record Dec. 3 and issued Feb. 20. The Commission vote to issue the consent was 4-1, with Commissioner Mary L. Azcuenaga dissenting. (Docket No. C-3208)

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-326-2179

(2step)

Aquanautics Corp.

OFFICE OF PUBLIC AFFAIRS
[illegible]

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. [illegible]

FOR YOUR INFORMATION..........November 25, 1986

CORRECTION

The date of publication in the Federal Register of a notice containing the FTC's consent agreement with Aquanautics Corp. has been changed to Nov. 28. The Commission will accept comments for 60 days, until Jan. 27, 1987.

The consent agreement was originally scheduled to appear on Nov. 25. The comment period was scheduled to end on Jan. 26.

# # #

MEDIA CONTACT: Linda L. Singer, Office of Public Affairs, 202-326-2178

(AQUA2)

Aquanautics Corp. final consent 2/17/87
D. C-3207

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: November 21, 1986

FTC CHARGES THAT THE MANUFACTURER OF A MARINE SURVIVAL SUIT MISREPRESENTED ABILITY OF ITS PRODUCT TO KEEP WEARERS AFLOAT

Company Agrees To Tell Users Of Life-Threatening Defect And To Provide Free Repair Kits

The Federal Trade Commission has charged that the manufacturer of a marine survival suit falsely claimed its product would keep users afloat in cold and rough waters for long periods of time and would decrease the likelihood of drowning. In fact, according to the Commission, the product had a safety defect that was potentially life threatening.

The San Francisco company, Aquanautics Corp., has signed a consent agreement under which it will notify owners and users of its Imperial Model 1409 survival suit of the possible failure of the suit. It will also send each user a free kit that can be used to retrofit the suit so that it works as intended. The kit consists of tie-down straps to secure a crucial part.

The suit, which is made of a buoyant material, has an inflatable collar, called a high-rider ring, that allows the wearer to keep head and shoulders upright in the water. The wearer must blow up the ring through a flexible hose, which the Commission alleges was not firmly attached to the ring and could seperate upon use.

A recent drowning off the Virginia coast involved a commercial fisherman who was wearing a Model 1409. A National Transportation Safety Board investigation determined that the crucial hose had, in fact, separated from the ring.

Aquanautics sold the suits through its Imperial Manufacturing Co. subsidiary. At that time, Imperial was the largest U.S. manufacturer of survival suits. Aquanautics, which sold Imperial in 1985, is also prohibited from making false claims for any survival suit it sells in the future, under terms of the agreement.

The Model 1409 suit is a one-piece jumpsuit-like garment made of a buoyant material that completely covers the wearer, except for the eyes and nose. It is designed to protect the wearer from hypothermia and to provide flotation in emergencies involving immersion in the ocean for long periods of time. The suit was sold primarily for commercial use and was used, for example, by workers on offshore oil rigs and fishing boats. The suit was marketed as safety equipment through advertising claims such as:

- "Our suit gives you the thermal protection and buoyancy needed to stay alive for hours," and
- "A revolutionary advancement in life-saving devices, the Imperial Survival Suit gives you the flotation and warmth needed to survive the rigors of the cold, unforgiving ocean."

(More)

Under the consent order, Aquanautics must send a free repair kit to any user or purchaser it can identify, and the company is required to take certain measures to locate them. The company must, among other things, ask all its retailers and distributors for the names and addresses of purchasers in their files. In addition, the company must place advertisements in appropriate publications warning of possible user injury and of the availability of the free repair kit.

The company will also send notices to the approximately 8,000 commercial fishing boat owners in Alaska who have state permits. Alaska has a high concentration of commercial fishermen in isolated areas who might not hear about the problem through other channels.

Between 1975 and March 1980, Imperial Manufacturing sold approximately 18,000 Model 1409 survival suits. Model 1409 suits sold after March 1980 were equipped with properly secured inflator hoses and are not covered by the agreement. The suits cost approximately $250 to $350.

The consent agreement is scheduled to appear in the Federal Register Nov. 25. It will be subject to public comment for 60 days, until Jan. 26, 1987, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Linda I. Singer, Office of Public Affairs, 202-326-2178

STAFF CONTACT: Theodore H. Hoppock, Bureau of Consumer Protection, 202-376-8648

(IMPERIAL)

(FTC File No. 852 3235)

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: January 29, 1987

FTC CHAIRMAN OLIVER VOWS TO COMBAT PRIVATE AND GOVERNMENT ANTITCOMPETITIVE PROBLEMS IN HEALTH CARE INDUSTRY

Federal Trade Commission Chairman Daniel Oliver today said that the Commission will continue to "attack governmental restraints on competition" in the health care industry, as well as challenging anticompetitive actions by industry members.

He told the National Health Lawyers' Association annual meeting in Washington that "This nation now spends more than 10 percent of its GNP on health care," and spent more in 1985 on health care than on national defense. Mr. Oliver added that "Marketplace medicine, or competition, is the best antidote to the high cost of health care in America."

"Nowhere does government interfere with the market more than in the health care sector," Mr. Oliver said. And "government regulation of health care generally has not worked."

Mr. Oliver said that the FTC's attack on regulatory restraints "has two components: to eliminate existing anticompetitive government regulations; and to block the imposition of new, unnecessary regulations that stifle competition and consumer choice."

For example, he cited "the futile attempts federal, state, and local governments have made in requiring 'Certificates-of-Need' before allowing private parties to spend their own money to construct their own hospitals and other health care facilities." There is little evidence to suggest that such requirements have helped to reduce costs or improve services, Mr. Oliver said, adding it is time for state and local governments to reevaluate whether central planning is more efficient than the market itself.

Another area of interest to the FTC, Mr. Oliver said, was the government's role as a third-party payer of health care services. The FTC has filed several comments with the Department of Health and Human Services analyzing proposed revisions in the health care reimbursement system. "We will continue to be the consumer's advocate to assure that the role of competition is given adequate weight in future efforts to rationalize government funding of health care."

He also said that the Commission will continue to oppose government regulations "likely to injure health care consumers by stifling innovative forms of competition." Such regulations might include those that discourage physicians from dispensing prescription drugs, or limit pharmacies' ability to transfer prescriptions by computer from one pharmacy outlet to another.

(More)

The Commission will also continue to challenge private anticompetitive actions within the health care industry itself, he said. "Among the most common — and significant — are those among otherwise competing providers not to engage in truthful advertising." Truthful advertising helps consumers by giving them valuable information, he noted, and "That's why we've been so active in challenging private, so-called 'ethical' restrictions" on such advertising.

Another area of FTC interest in the private sector is attempts by one group of health care providers to prevent another group from furnishing similar services, even though permitted by state law. For example, he said, obstetricians may attempt to prevent general practitioners from delivering babies.

Other areas the Commission might challenge include private abuse of the courts and governmental proceedings to disadvantage competitors, such as attempts to delay entry by a competitor. The FTC will also challenge anticompetitive efforts by groups of health care professionals to collude to undermine cost-containment efforts.

Mr. Oliver concluded: "I am not in favor of competition and the free market only because the market works. Our goal is not merely to improve our material life. We favor the free market, because we favor freedom. We know that economic freedom is not separable from political freedom. Economic freedom is one of our political freedoms — like the freedom to worship, and the freedom to speak. And our goal always should be to extend that freedom as much as we can to both consumers and producers — to providers and to patients."

Copies of the speech are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Richard MacGowan, Office of Public Affairs,
202-326-2180

(DOHealth)

Puritan-Bennett Aero Systems Co. C-3217
Final Consent 8/25/87

OFFICE OF PUBLIC AFFAIRS
[illegible]

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

FOR YOUR INFORMATION..................September 22, 1987

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

- C-3217
  Puritan-Bennett Aero Systems Co. The consent order settles FTC charges that the company, which sells fire- and smoke-protection masks, failed to disclose in its ads that the masks do not filter carbon monoxide, probably the most dangerous gas encountered in fires. Under the consent order, the company may not make deceptive advertising claims for such products in the future.

  A consent agreement was placed on the public record June 3 and the consent order issued August 25. (Docket No. C-3217)

- Alleghany Corp. The consent order settles FTC charges that Alleghany's acquisition of Safeco Title Insurance Co. could have substantially reduced competition in the production and sale of title information in Cook County, Ill., and Los Angeles County, Calif. A consent order requires that Alleghany divest two title plants. The vote to accept the consent order was 3-2, with Commissioners Patricia P. Bailey and Mary L. Azcuenaga dissenting.

  A consent agreement was placed on the public record Feb. 3 and the consent order issued Sept. 8. (Docket No. C-3216)

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 326-2180

FOR YOUR INFORMATION........................April 28, 1987

The Federal Trade Commission staff has recommended that the Virginia State Board of Dentistry adopt proposed new regulations "that would eliminate many of the most troublesome advertising prohibitions," but said that "some further amendments are appropriate."

In a letter to the Board, the staff said it supported proposals to lift bans on the use in advertising of representations of quality, testimonials, statements of specialization, and certain other claims by general dentists. These changes "will broaden the scope of useful information that dentists may advertise, and will thereby benefit consumers," according to staff.

However, the staff recommended that the Board eliminate its proposed rules that would limit offers of discount prices and fee advertising for nonroutine services. The FTC staff also urged the Board to adopt "a more flexible standard of supervision" by dentists of dental hygienists.

In addition, the FTC staff recommended that the Board ask the state legislature to remove provisions which prohibit dentists from practicing under a trade name; ban employment and other business relationships between dentists and non-dentists; and prohibit dentists from leasing space from any commercial establishments. The staff also urged the Board to seek the removal of restrictions on the development and operation of prepaid dental plans.

In conclusion, the staff said, "we urge the Board to consider the consumer harm that may come from restrictions on truthful, nondeceptive advertising, on commercial forms of practice, and on prepaid dental plans. Such restrictions tend to raise prices and decrease the quality of care."

The letter represents the views of the FTC's Bureaus of Consumer Protection, Competition, and Economics, and does not necessarily reflect the views of the Commission or any individual Commissioner.

Copies of the letter are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-326-2179
STAFF CONTACT:	Matthew Daynard, Bureau of Consumer Protection, 202-326-3291

(VaDent)

FOR YOUR INFORMATION..................May 4, 1987

The Federal Trade Commission staff has told the Tennessee Board of Dentistry that it supports the Board's efforts "to broaden the scope of permissible advertising by dentists, and with certain reservations ... we urge the Board to adopt the proposed rules."

The State Board is considering amendments to its rules on dentists' advertising.

In a letter to the Board, the staff said: "The proposed rules represent a substantial improvement over the Board's existing regulations. They would eliminate many provisions that now appear to impede the communication of nondeceptive information to consumers. However, we believe there are certain additional changes that would still further enhance the rules' benefits for consumers." The staff recommended that the Board:

- require only the disclosures "that are necessary to prevent deception of the public" when dentists advertise a range of fees;
- modify a prohibition on referral fees so that dentists are not prevented from participating in legitimate referral services and alternative health care delivery systems;
- allow all dentists with verifiable expertise to advertise that information; and
- require that only those employees who have "control or management of a firm" be held accountable for advertising decisions.

The letter represents the views of the FTC's Bureaus of Consumer Protection, Competition, and Economics, and does not necessarily reflect the views of the Commission or any individual Commissioner.

Copies of the letter are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-326-2179
STAFF CONTACT:	David Spiegel, Bureau of Consumer Protection, 202-326-3281

(TennDent)

Puritan-Bennett Aerosystems Co.

FTC news

Federal Trade Commission ***Washington, D.C. 20580*** Final 8/25/87

FOR IMMEDIATE RELEASE: May 28, 1987

SELLER OF FIRE- AND SMOKE-PROTECTION MASKS MAY NOT MAKE DECEPTIVE CLAIMS, UNDER CONSENT AGREEMENT WITH FTC

The Federal Trade Commission has charged a company that sells fire- and smoke-protection masks with deceptive advertising for failing to disclose the masks do not filter carbon monoxide, probably the most dangerous gas encountered in fires. Under a consent agreement issued today for public comment, Puritan-Bennett Aero Systems Co. may not make deceptive advertising claims for such products in the future.

Puritan-Bennett Aero Systems, a Calif.-based company, advertised and sold its "Escape Fire and Smoke Hood" to consumers by direct mail for $49.50 each. The Escape Hood fits over the user's head and is intended to protect him or her from smoke and gases resulting from fire. Trade sources estimate total company sales at about $8 million annually.

Puritan-Bennett Aero Systems claimed in ads and promotional materials that the Escape Hood provided effective protection against the hazards associated with fire for a reasonable amount of time, and that it absorbed almost all noxious and toxic gases. In fact, according to a complaint issued with the consent agreement, these claims are deceptive because the Escape Hood does not absorb or filter carbon monoxide, a lethal gas produced in all fires. The complaint also charged that Puritan-Bennett Aero Systems's failure to disclose this fact to consumers was deceptive.

Under the consent agreement, Puritan-Bennett Aero Systems may not make certain claims in its ads unless the claim is true and supported by a reliable scientific test. The company must have such substantiation for claims that any emergency escape mask or hood can absorb, remove or filter out any hazardous gas associated with fire, or that any mask or hood can protect users from any fire hazards.

In addition, the consent agreement requires that if the company claims in broadcast or print ads or in promotional materials that the Escape Hood — or any other emergency mask or hood that cannot remove carbon monoxide — can protect the user from any hazard associated with fire, it must include the following notice: "This device does not filter carbon monoxide — a lethal gas associated with fire." In addition, a similar disclosure must all appear on all package labels.

The consent agreement requires the company to retain for three years all test reports, studies or other materials it uses as substantiation for any covered claims.

According to the FTC staff, Puritan-Bennett Aero Systems advertised the Escape Hood from April through July of 1985. Puritan-Bennett Aero Systems, with headquarters in El Segundo, Calif., is a wholly owned subsidiary of Puritan-Bennett Corp. of Overland Park, Kansas. Puritan-Bennett Corp., although not charged in the complaint, has agreed to be bound by the terms of the consent agreement.

(More)

The consent agreement is scheduled to appear in the Federal Register June 3. It will be subject to public comment for 60 days, until August 3, after which the Commission will decide whether to make it final.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

STAFF CONTACT: Joel Winston, Bureau of Consumer Protection, 202-326-3153

FTC File No. 852 3238

[puritan]

New Medical Techniques, Inc. C-3220
Final consent 11/18/87

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 326-2180

FOR YOUR INFORMATION..................December 10, 1987

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

- Jerome Milton, Inc. The consent agreement settles charges that the company deceptively claimed its toothpaste cures gum disease and is superior to other toothpastes in reducing plaque. The agreement was placed on the public record August 10 and issued October 26. (Docket No. 9187)
- Tarrant County Medical Society. The consent agreement settles charges that the society illegally restricted truthful advertising by its physician members. The agreement was placed on the public record August 10 and issued November 2. (Docket No. C-3219)
- New Medical Techniques, Inc. The consent agreement settles charges that the company misrepresented that its water purification device had been endorsed by various organizations, will protect users from health hazards, is capable of removing any impurities from water, and will provide absolutely pure water. The agreement was placed on the public record June 15 and issued November 18. (Docket No. C-3220)

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Brenda A. Mack, Office of Public Affairs,
202-326-2180

(2ndStep)

New Medical Techniques Inc.

FTC news

Federal Trade Commission *Washington, D.C. 20580* Final 11/18/89

FOR IMMEDIATE RELEASE: June 15, 1987

FTC CHARGES CONNECTICUT FIRM WITH FALSE CLAIMS ON WATER DISTILLER; COMPANY AGREES TO CHANGE ADS

The Federal Trade Commission today charged a Connecticut company with using deceptive advertising for its water distillers. The firm agreed not to misrepresent the ability of its devices to provide pure water, under a consent agreement announced today.

The company, New Medical Techniques Inc. (NMT) of Mystic, Conn., manufactures and distributes countertop water distillers. In a complaint filed with the consent agreement, the FTC said the water distillers are designed to remove contaminants from water by boiling and recondensing the water.

The complaint said NMT claimed, in its promotional literature, that its water distillers removed all chemicals and impurities from tap water and provided a user with absolutely pure and safe water. The firm also claimed its distillers were tested and endorsed by the U.S. Public Health Service and Duke University Medical Center.

The FTC's complaint alleged that those claims were false and unsubstantiated because NMT's distillers failed to remove potentially carcinogenic volatile organic chemicals (VOCs). VOCs are found in industrial and pesticide wastes, which can enter water supplies. Some VOCs include benzene, methylene chloride, and chloroform.

In addition, the Commission's complaint charged that neither Duke University Medical Center nor the U.S. Public Health Service had tested or endorsed NMT's distillers.

The order would prohibit NMT from making any false or deceptive claims about the ability of any water purification device to remove chemicals or other contaminants from water or to protect users from hazards caused by such contaminants. The order also requires that NMT refrain from falsely representing that such devices are approved or endorsed by any person or organization.

The order would require NMT to possess scientific data before making any claims that its water purification devices will provide absolutely pure water, protect users from particular health hazards, or remove contaminants or chemicals from water.

The order also contains a disclosure requirement that applies in most instances when the company claims generally in its advertising that its water purification devices will remove chemical contaminants. The disclosure must say that the device is not designed to remove potentially hazardous VOCs. The disclosure requirement does not apply when the company only mentions specific chemicals that the device will, in fact, remove.

(more)

The consent agreement is scheduled to appear in the Federal Register June 16. It will be subject to comment for 60 days, until August 17, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order can result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th Street and Pennsylvania Avenue N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Jim Pinkelman, Office of Public Affairs 202-326-2178
STAFF CONTACT:	Joel Winston, Bureau of Consumer Protection 202-326-3153

(FTC File No. 852 3121)

(NewMed)

Jerome Milton Inc. D. 9187 final consent
10/26/87

OFFICE OF PUBLIC AFFAIRS
(202) 326-2180

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

FOR YOUR INFORMATION..................December 10, 1987

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

- Jerome Milton, Inc. The consent agreement settles charges that the company deceptively claimed its toothpaste cures gum disease and is superior to other toothpastes in reducing plaque. The agreement was placed on the public record August 10 and issued October 26. (Docket No. 9187)
- Tarrant County Medical Society. The consent agreement settles charges that the society illegally restricted truthful advertising by its physician members. The agreement was placed on the public record August 10 and issued November 2. (Docket No. C-3219)
- New Medical Techniques, Inc. The consent agreement settles charges that the company misrepresented that its water purification device had been endorsed by various organizations, will protect users from health hazards, is capable of removing any impurities from water, and will provide absolutely pure water. The agreement was placed on the public record June 15 and issued November 18. (Docket No. C-3220)

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Brenda A. Mack, Office of Public Affairs,
202-326-2180

(2ndStep)

Jerome Milton Inc.

FTC news

Federal Trade Commission *Washington, D.C.* 20580

Final 10/26/87

FOR IMMEDIATE RELEASE: August 10, 1987

MAKER OF SHANE TOOTHPASTE MUST HALT DECEPTIVE ADS, AND SUBSTANTIATE CLAIMS IN THE FUTURE, UNDER AGREEMENT WITH FTC

The Federal Trade Commmission announced today that the maker of Shane toothpaste has agreed to settle charges it deceptively claimed its toothpaste cures gum disease and is superior to other toothpastes in reducing plaque. Under a consent agreement issued today for public comment, Jerome Milton Inc. agreed to have substantiation for such claims in the future.

The consent agreement settles a 1984 FTC complaint charging the company and Jerome Milton Schulman, an officer of the company, did not have substantiation to support its advertising claims for the toothpaste.

Under the agreement, Milton may not claim that Shane cures or alleviates the symptoms of canker or cold sores, or reduces tooth sensitivity, unless it has at least one well-controlled clinical test to substantiate the claim. In addition, the company must rely on one or more scientifically-accepted tests or studies for claims that the toothpaste is useful in the diagnosis, cure, mitigation, treatment, or prevention of any disease.

Milton must have at least two well-controlled clinical tests to substantiate claims that the product reduces plaque more effectively than any other oral hygiene product or that it cures or alleviates gingivitis or periodontitis, under the agreement.

The company and individual both do business in Chicago.

The consent agreement is scheduled to appear in the Federal Register Aug. 10. It will be subject to public comment for 60 days, until Oct. 8, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-326-2179
STAFF CONTACT:	William Haynes, Bureau of Consumer Protection 202-326-3088

(FTC Docket No. 9167)
(Shane2)

Jerome Milton Inc. complaint

FTC

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: September 25, 1984

CLAIMS THAT SHANE TOOTHPASTE TREATS GUM DISEASE AND REDUCES PLAQUE ARE UNSUBSTANTIATED, FTC COMPLAINT CHARGES

There is no evidence substantiating advertising claims that Shane toothpaste cures gum disease or is superior to other toothpastes in reducing plaque, the Federal Trade Commission charged in an administrative complaint today.

According to the complaint, Jerome Milton Inc. and Jerome Milton Schulman, an officer of the company, deceptively claimed that:

— the use of Shane will cure or ease the symptoms of canker sores, cold sores and gum problems associated with gingivitis and periodontitis;

— Shane is superior to other toothpastes in reducing or eliminating plaque; and

— the use of Shane will lessen the sensitivity of the teeth to hot and cold substances.

The toothpaste costs $5.95 a tube.

The Commission issues a complaint when it has "reason to believe" that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon by an administrative law judge after a formal hearing.

If the judge finds the company violated the law, and the Commission affirms that decision, the agency can take any of several actions listed in a notice of contemplated relief accompanying the complaint. It could order Milton to have competent and reliable evidence before claiming Shane or any other toothpaste or oral hygiene product:

— cures or alleviates specific symptoms;

— reduces plaque more effectively than any other toothpaste or oral hygiene product;

— reduces the sensitivity of teeth to hot or cold substances; or

— has any other therapeutic property.

The company is based in Chicago.

(More)

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1892.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-523-1892
STAFF CONTACT:	William Haynes, Bureau of Consumer Protection, 202-376-8720

(File No. 842-3044)

(shane)

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: August 10, 1987

FTC CHARGES TEXAS' TARRANT COUNTY MEDICAL SOCIETY RESTRICTED DOCTORS' ADS; SOCIETY SETTLES CHARGES

The Federal Trade Commission today charged that the Tarrant County (Texas) Medical Society illegally restricted truthful advertising by its members. Under a consent agreement, the society agreed not to restrict such advertising in the future.

The society has approximately 1,300 members and is based in Fort Worth, Texas.

According to a complaint accompanying the agreement, the society, through its Board of Censors, restricted its members' advertising through a number of limitations on the amount, duration, and size of newspaper ads.

The complaint charged that these restrictions hurt competition among physicians and deterred them from advertising truthful information. In addition, consumers were deprived of truthful information about physicians' prices, services, and qualifications, according to the complaint.

Under the consent agreement, the society agreed not to restrict, regulate or declare unethical any doctor's truthful advertising.

The society further agreed, for 10 years, to provide written notice to any doctor whose advertising it intends to challenge, and to allow that doctor a reasonable opportunity to respond.

The consent agreement is scheduled to appear in the Federal Register Aug. 10. It will be subject to public comment for 60 days, until Oct. 9, after which the Commission will decide whether to make it final.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, same address; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-326-2179
STAFF CONTACT:	Elizabeth Gee, Bureau of Competition, 202-326-2756

(FTC File No. 861 0050) (Tarrant)

J008918

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of TARRANT COUNTY MEDICAL SOCIETY, a corporation.	FILE NO. 861-0050 AGREEMENT CONTAINING CONSENT ORDER TO CEASE AND DESIST

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent Tarrant County Medical Society (TCMS), and it now appearing that TCMS is willing to enter into an agreement containing an order to cease and desist from the use of the acts and practices being investigated,

IT IS HEREBY AGREED by and between TCMS and its duly authorized officer and/or its attorney, and counsel for the Federal Trade Commission that:

1. TCMS is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its mailing address at 3855 Tulsa Way, Fort Worth, Texas 76107.

2. TCMS admits all of the jurisdictional allegations set forth in the draft of complaint here attached.

3. TCMS waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and

(d) Any claim under the Equal Access to Justice Act.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify TCMS, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by TCMS that the law has been violated as alleged in the draft of complaint here attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules of Practice, the Commission may, without further notice to TCMS, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding, and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to TCMS's address stated in this agreement shall constitute service. TCMS waives any right it may have to any other manner of service. The complaint attached hereto may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. TCMS has read the proposed complaint and order contemplated hereby. It understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the order. TCMS further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after the order becomes final.

ORDER

I.

For purposes of this order, the following definitions shall apply:

A. "TCMS" means respondent Tarrant County Medical Society, its officers, councils, committees, boards, representatives, agents, employees, successors, and assigns; and

B. "Adverse action" means the revocation or suspension of, or refusal to grant, membership in TCMS, or the disciplining or penalizing of any physician.

II.

IT IS ORDERED, that TCMS, directly or indirectly, or through any device, shall forthwith cease and desist from:

Restricting, regulating, declaring unethical, impeding, interfering with, or advising against the advertising or publishing by any person or organization of information about the prices, terms, or conditions of sale of physicians' services, or of any information about physicians' services, facilities, or equipment which are offered for sale or made available by physicians or by any organization with which physicians are affiliated, including but not limited to restricting or attempting to restrict the content, format, size, or frequency of any such advertisements or publications.

Nothing contained in this order shall prohibit TCMS from formulating, adopting, disseminating to its members, and enforcing reasonable ethical guidelines governing the conduct of its members with respect to representations, including unsubstantiated representations, that TCMS reasonably believes would be false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act.

III

IT IS FURTHER ORDERED, that TCMS shall cease and desist from:

A. For a period of ten (10) years after service of this order, taking any adverse action against a person alleged to have violated any rule, policy, guideline, or ethical standard relating to physician advertising without first providing such person with written notice of the allegations against such person and without providing such person a reasonable opportunity to respond. The notice required by this part shall, at a minimum, clearly specify the rule, policy, guideline, or ethical standard alleged to have been violated, the specific conduct that is alleged to have violated the rule, policy, guideline, or ethical standard, and the reasons the conduct is alleged to have violated the rule, policy, guideline, or ethical standard; and

B. Failing to maintain for five (5) years following the taking of any action referred to in this part of the order, in a separate file segregated by the name of any person against whom such action was taken, any document that embodies, discusses, mentions, refers, or relates to the action taken and any allegation relating to it.

IV.

IT IS FURTHER ORDERED, that TCMS shall:

A. For a period of five (5) years, commencing on the date this order is served, provide each applicant for membership in TCMS with a copy of this order at the time the applicant applies for membership;

B. Within sixty (60) days after service of this order, publish a copy of the complaint and this order in the Physician, or in any successor publication, with the same prominence as regularly published feature articles;

C. Within fifteen (15) days after service of this order, remove from TCMS' documents entitled "Board of Censors Agenda for Meeting with Provisional Members" and "Board of Censors Meeting with Applicants for Membership," and any other existing ethical or policy statement or guideline of TCMS, any provision, interpretation or statement which is inconsistent with Part II of this order, and within sixty (60) days after service of this order, publish, in the manner described in Part IV.B. of this order, a copy of the revised versions of such statements, guidelines, or interpretations to each of its members;

D. Within sixty (60) days after service of this order, send to the Southwest Bell Telephone Company supervisor in charge of professional advertising a copy of this order and accompanying complaint;

E. Within ninety (90) days after service of this order, and at any time the Commission, by written notice, may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which TCMS has complied with this order; and

F. For a period of five (5) years after service of this order, maintain and make available to the Commission staff for inspection and copying upon reasonable notice, records adequate to describe in detail any action taken in connection with the activities covered by Parts II and III of this order, including but not limited to any advice or interpretation rendered with respect to advertising involving any physician.

V.

IT IS FURTHER ORDERED, that TCMS shall notify the Commission at least thirty (30) days prior to any proposed change in the respondent, such as dissolution or reorganization resulting in the emergence of a successor corporation or association, or any other change in the corporation or association which may affect compliance obligations arising out of this order.

Signed this 26 day of June 1987.

APPROVED:

M. Elizabeth Gee
M. Elizabeth Gee
Assistant Director
Bureau of Competition

Barbara A. Clark
~~Jeffrey Zuckerman~~
Acting Director
Bureau of Competition

TARRANT COUNTY MEDICAL SOCIETY,
a corporation.

By G. D. Tatum Jr MD
President, Tarrant County
Medical Society

William B. David
William B. David, Esquire
Attorney for Tarrant
County Medical Society

COUNSEL FOR FEDERAL TRADE
COMMISSION

L. Barry Costilo
L. Barry Costilo

Linda M. Brody
Linda M. Brody

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of TARRANT COUNTY MEDICAL SOCIETY, a corporation.	Docket No.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended (Title 15, U.S.C. § 41 *et seq.*), and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that the named respondent has violated the provisions of Section 5 of the Federal Trade Commission Act and that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint, stating its charges as follows:

PARAGRAPH ONE: Respondent Tarrant County Medical Society is a corporation formed pursuant to the laws of the State of Texas, with its mailing address at 3855 Tulsa Way, Fort Worth, Texas 76107.

PARAGRAPH TWO: Respondent is a professional association formed to represent the interests of physicians who practice in Tarrant County, Texas. Respondent has approximately 1,300 members, constituting a substantial majority of the physicians in Tarrant County.

PARAGRAPH THREE: Respondent is a component society of the Texas Medical Association, which in turn is a constituent society of the American Medical Association.

PARAGRAPH FOUR: Members of respondent are engaged in the business of providing medical health care services for a fee. Except to the extent that competition has been restrained as herein alleged, members of respondent have been and are now in competition among themselves and with other physicians.

PARAGRAPH FIVE: Respondent engages in substantial activities which further its members' pecuniary interests. By virtue of its purposes and activities, respondent is a corporation within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

PARAGRAPH SIX: In the conduct of their business, members of respondent receive substantial sums of money, which flow across state lines, from the federal government and from private insurers for rendering medical services, and purchase equipment and supplies and prescribe medicines which are shipped in interstate commerce. The acts or practices described below are in interstate commerce, or affect the interstate activities of respondent's members, third-parties who pay for medical services, other third parties, and some patients of respondent's members, and are in or affect commerce within the meaning of Section 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1).

PARAGRAPH SEVEN: Respondent has acted as a combination of at least some of its members or has conspired with at least some of its members to hinder, frustrate, or restrict competition among physicians in Tarrant County by restricting or attempting to restrict its members from disseminating information to consumers through truthful, non-deceptive advertising.

PARAGRAPH EIGHT: Respondent has engaged in various acts and practices in furtherance of this combination or conspiracy, including:

A. Through its Board of Censors, restricting or attempting to restrict the amount, duration, and size of advertising announcements that members place in newspapers. For example, respondent distributed restrictions to members that limit advertising announcements in newspapers to ten days and one-column inch in size; and

B. Through its Board of Censors, restricting or attempting to restrict the number of telephone directory listings its members place and the size of their print.

PARAGRAPH NINE: The purposes or effects of the combination or conspiracy and acts or practices of respondent as described above have been and are to unreasonably restrain competition and injure consumers in one or more of the following ways, among others:

A. Vigorous competition among physicians is impeded;

B. Physicians are being deterred from advertising truthful information in the media about their prices, services, and qualifications; and

C. Consumers are being deprived of receiving truthful information about physicians' prices, services, and qualifications.

PARAGRAPH TEN: The combination or conspiracy and the acts and practices described above constitute unfair methods of competition and unfair acts or practices which violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination or conspiracy is continuing and will continue absent the entry against respondent of appropriate relief.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission, on this _______ day of _____________, 1987, issues its complaint against the Tarrant County Medical Society.

By the Commission.

SEAL

Emily H. Rock
Secretary

TARRANT COUNTY MEDICAL SOCIETY

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed consent order from the Tarrant County Medical Society ("Medical Society") located in Ft. Worth, Texas. The agreement would settle charges by the Commission that the proposed respondent violated Section 5 of the Federal Trade Commission Act by combining or conspiring to interfere with competition among physicians in Tarrant County by restricting its members from disseminating information to consumers through truthful, non-deceptive advertising.

The proposed consent order has been placed on the public record for 60 days for reception of comments by interested persons. Comments received during this period will become part of the public record. After 60 days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The Complaint

A complaint has been prepared for issuance by the Commission along with the proposed order. It alleges that in furtherance of this conspiracy, the Medical Society, through its Board of Censors, has restricted the amount, duration and size of advertising announcements that its members place in newspapers. The complaint alleges, for example, that the Medical Society distributed restrictions to members that limit advertising announcements in newspapers to 10 days and one-column inch in size.

In addition, the complaint alleges that through its Board of Censors, the Medical Society has attempted to restrict the number of telephone directory listings its members place and the size of their print.

The complaint further alleges that the purposes or effects of the combination or conspiracy have been to restrain trade unreasonably and injure consumers in the following ways among others:

A. Vigorous competition among physicians is impeded;

B. Physicians are being deterred from advertising truthful information in the media about their prices, services, and qualifications; and

C. Consumers are being deprived of receiving truthful information about physicians' prices, services, and qualifications.

The Proposed Consent Order

Part I of the proposed consent order contains definitions of terms used in the order.

Parts II of the order prohibits the Medical Society from interfering with, restricting, or advising against the advertising or publishing of information about the prices, terms, or conditions of sale of physicians' services by physicians or organizations with which physicians are affiliated, including restricting the content, format, size, or frequency of such advertisements or publications.

Part II of the order also contains a proviso stating that the order does not prohibit the Medical Society from formulating or enforcing reasonable ethical guidelines with respect to advertising by the Society's members that is false or deceptive under Section 5 of the Federal Trade Commission Act.

Part III.A. of the proposed consent order requires that the Medical Society, before taking any adverse action against any person alleged to have violated any Medical Society policy or ethical standard relating to physician advertising, provide that person with written notice of the allegation and a reasonable opportunity to respond. Part III.B. requires the Medical Society to maintain a file relating to any such adverse action for 5 years.

Part IV.A. requires, for a period of five years, that the Medical Society give each applicant for membership a copy of the order. Part IV.B. requires, within 60 days after service of the order, that the Medical Society publish a copy of the complaint and order in its publication, the Physician.

Part IV.C. of the proposed consent order requires the Medical Society, within 15 days after service of the order, to remove from Medical Society documents entitled "Board of Censors Agenda for Meeting with Provisional Members" and "Board of Censors Meeting with Applicants for Membership", and any other ethical or policy statement or guideline of the Medical Society, any provisions that are inconsistent with Part II of the order.

Part IV.D. requires the Medical Society to send a copy of the order and accompanying complaint to the Southwest Bell Telephone Company supervisor in charge of professional advertising.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Sun Industries, Inc. C-3230
final consent 5/13/88

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 326-2180

FOR YOUR INFORMATION..................June 22, 1988

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

- NEC Home Electronics (U.S.A.) Inc. The consent agreement settles charges that a computer company deceptively advertised the memory capacity of its desktop microcomputer. The agreement also requires the company to pay $15,000 in redress to about 100 consumers. The agreement was placed on the public record March 2 and issued May 11. (Docket No. C-3229)

- X Sun Industries, Inc. The consent agreement settles charges that a manufacturer of artificial tanning devices misrepresented the safety of its products by making false claims that its products do not pose the risk of skin damage, including the risk of skin cancer. The agreement was placed on the public record December 23, 1987, and issued May 13, 1988. (Docket No. C-3230)

- Medical Staff of Memorial Medical Center. The consent agreement settles charges that the medical staff of a hospital in Savannah, Ga., illegally denied hospital privileges to a nurse-midwife, without having any reasonable basis for the denial. The agreement was placed on the public record January 21 and issued June 1. (Docket No. C-3231)

  Chairman Daniel Oliver issued a separate statement, in which he concurred in accepting the consent order, but argued that the order should terminate automatically after ten years.

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Brenda A. Mack, Office of Public Affairs,
202-326-2180

(2Step)

Sun Industries Inc. C-3230

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: December 17, 1987

FTC CHARGES MANUFACTURER OF SUNTANNING DEVICES FALSELY CLAIMED THAT ITS PRODUCTS DO NOT INCREASE THE RISK OF SKIN CANCER; CONSENT AGREEMENT PROHIBITS FALSE AND UNSUBSTANTIATED CLAIMS

The Federal Trade Commission has charged one of the country's largest manufacturers of artificial tanning devices with making false claims that its products do not pose the risk of skin damage, including the risk of skin cancer. A consent agreement issued today for public comment prohibits Sun Industries Inc. from misrepresenting the safety of its products.

Sun Industries manufactures and sells tanning devices and related products, including tanning beds, facial units, and overhead lamp systems. According to the FTC staff, Sun Industries markets its products to tanning salons, health clubs, and beauty salons as well as to individuals, primarily through independent distributors located throughout the country. It markets its products under such trade names as SunTana SunSystem and SunMate.

In magazine, television and radio ads, as well as in promotional literature, Sun Industries made claims such as: "Enjoy the luxury and convenience of a proven and safe UVA tanning system. Other ads claim, "For efficient tanning year 'round without the harmful side effects often associated with natural sunlight." In addition, the company claimed in some ads, "There's no harsh glare, so no goggles or eye shades are necessary."

According to a complaint issued with the consent agreement, these claims are false. Specifically, according to the complaint, Sun Industries falsely claimed in ads and promotional materials:

- that its devices could be used without risking the harmful side effects associated with exposure to the sun, including the risk of developing skin cancer;
- that its devices could be used safely without eye protection; and
- that it had reliable scientific evidence for its claims.

In addition, the complaint charges, Sun Industries acted deceptively when it used such terms as "safe" and "no harmful side effects," but failed to disclose the risk of eye injury and the increased risk of skin cancer and skin aging.

In fact, according to the complaint, use of Sun Industries' products can increase the risk of developing skin cancer, its devices cannot be used without the risk of any harmful side effect associated with the sun, and they cannot be used safely without protective eyewear. The consent agreement prohibits the company from misrepresenting that use of a tanning device does not pose a risk of any harmful side effect to the user.

(More)

The complaint charged that Sun Industries falsely claimed it had a reasonable basis for its claims. Under the consent agreement, the company must have reliable and competent scientific evidence for any health or safety claim it makes in any advertisement.

For one year after the consent is made final, Sun Industries must include the following statement in any ads and promotional materials for its tanning devices, "NOTICE — Read the mandatory FDA warning label found on every tanning machine for important information on potential eye injury, skin cancer, skin aging and photosensitive reactions." After the first year, the company must include that statement in any ads that claim its tanning device is safe or safer than other devices or other methods of tanning, or that the device has health benefits.

Sun Industries Inc. is based in Jonesboro, Ark.

The consent agreement is scheduled to appear in the Federal Register Dec. 23. It will be subject to public comment until Feb. 22, 1988, after which the Commission will decide whether to make it final.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

STAFF CONTACT: C. Lee Peeler, Bureau of Consumer Protection, 202-326-3090

FTC File No. 852 3213

[sun]

Great Earth International [illegible] 3/15/88

NEW CONSUMER BROCHURE

With credit card usage on the increase, a form of credit fraud is also growing. It is called "credit repair," and its practitioners claim they are able to take a bad credit record and quickly make it good again — for a fee.

However, the Federal Trade Commission is finding that fraudulent companies advertising an ability to "erase" a bad credit record may do nothing more than take consumers' money and vanish.

Because credit repair fraud is becoming a serious problem, the FTC has prepared a booklet to help consumers understand how to repair their own credit records. The booklet, called "Building A Better Credit Record," explains in simple terms the legal rights that consumers have under the Fair Credit Reporting Act. It explains how to understand a credit history, how a bill-paying record is collected and maintained, what a credit report looks like, and how consumers can do their own credit check-up at little or no cost.

The booklet provides information about terms that credit reports use and gives tips on how to improve a credit record. It suggests what steps to take if bills pile up or credit applications are turned down. Finally, the booklet gives help in evaluating the claims of credit repair companies and tells consumers where to report problems they have had with such companies.

For free single copies of "Building A Better Credit Record," write to: Public Reference Branch, Federal Trade Commission, Washington, D.C. 20580. For questions or comments, call the FTC's Office of Consumer and Business Education, 202-326-3268. (4/28/88)

FINAL APPROVAL TO CONSENT AGREEMENTS

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

- Preferred Physicians Inc. The consent agreement settles charges that an association of doctors in Tulsa, Okla., illegally conspired to restrain competition and fix or increase the prices they charged third-party payers for their services. The agreement was issued for public comment on December 2, 1987, and issued February 26, 1988. (Docket No. C-3222)

  In a concurring statement, Chairman Daniel Oliver said that while he had voted to issue the consent order, he "would have preferred an order that included a provision for automatic termination after ten years." The Chairman said that automatic termination was warranted because, in his view, the remedial benefits of the order could be expected to decline over time and it might begin to have adverse effects on competition.

- Great Earth International, Inc. The consent agreement settles charges that a franchisor of food supplement stores falsely claimed that three of its food supplements would enable users to lose weight, build muscle, or promote healing. The agreement was issued for public comment on January 5, 1988, and issued March 15, 1988. (Docket No. C-3223)

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000. (4/14/88)

NEW CONSUMER BROCHURE

With summer getting closer, families are planning their annual vacation, and many will be using the family car. That means thinking about maintenance to avoid problems, but responding to enticing advertisements for a transmission checkup sometimes ends up with a total overhaul — whether it's needed or not.

The Federal Trade Commission, in cooperation with the Automotive Parts Rebuilders Association, and the Automatic Transmission Rebuilders Association, has a free pamphlet called "Automatic Transmission Repair" available to inform consumers about the problem, what to look for to avoid it, and guidelines for proper care of a transmission.

For a copy of the brochure, consumers should send fifty cents to the Consumer Information Center, Pueblo, Colorado 81009. (5/2/88)

Great Earth International Inc.

FTC news

Federal Trade Commission *Washington, D.C. 20580* [illegible] Inc

FOR IMMEDIATE RELEASE: January 4, 1986

FRANCHISOR OF FOOD SUPPLEMENT STORES PROHIBITED FROM MAKING FALSE CLAIMS, UNDER CONSENT AGREEMENT WITH FTC

The Federal Trade Commission charged in a complaint that a franchisor of food supplement stores falsely claimed that three of its food supplements would enable users to lose weight, build muscle, or promote healing. A consent agreement settling the charges prohibits Great Earth International Inc. from making certain claims about the supplements' effectiveness.

Great Earth has about 150 retail outlets coast to coast, 140 of which are owned by franchisees and licensees and the remainder by the company. The Santa Ana, Calif.-based company sells food supplements, including pills, capsules, powders or liquids containing vitamins, minerals and other products. The company and its franchisors advertise their products throughout the United States. According to trade sources, Great Earth's sales in 1984 were about $45 million.

According to the complaint, Great Earth falsely claimed that three of its products would enable users to lose weight, build muscle, burn fat, promote healing, protect against mental and physical fatigue and strengthen the immune system. The company's ads stated that these benefits result because the products stimulate the body to release human growth hormone from the pituitary gland. However, the complaint charges the products do not stimulate the pituitary gland in that way and do not provide the promised results.

The company's ads for GHR Formula-P.M. claimed: "Lose while you snooze;" and "When you go to sleep, GHR Formula-P.M. goes to work burning away fat, building lean muscle tissue and firming." Great Earth is currently selling this product under the name "Tri-Amino Plus P.M." Great Earth's ads for L-Ornithine and L-Arginine claimed: "They help speed up healing and protect against physical and mental fatigue." The complaint charges that these claims are false.

Great Earth represented in its ads and promotional materials that it had substantiation for its claims but, according to the complaint, the company did not.

Under the consent agreement, Great Earth must have substantiation for claims that any product will:

— cure or prevent any disease or other undesirable physical or mental condition;

— assist a user in losing or controlling weight or fat;

— improve or strengthen any body organ or function; or

— eliminate or reduce any harmful substance or organisms that may be found in the body or environment.

(More)

In addition, the consent agreement prohibits Great Earth from making certain claims for GHR Formula-P.M., L-Ornithine, or L-Arginine, including claims that they will:

- stimulate production or release of human growth hormone;
- help users achieve rapid or substantial muscular development;
- promote weight loss during sleep; or
- promote burning of fat or building, firming or toning muscles.

The consent agreement also prohibits Great Earth from using the name "Growth Hormone Releaser," "GHR," or any similar name unless it has substantiation that the product stimulates the body or pituitary gland to release significantly greater amounts of human growth hormone in users than in non-users.

The FTC's Chicago Regional Office handled the investigation.

The consent agreement is scheduled to appear in the Federal Register Jan. 5. It will be subject to public comment until March 7, after which the Commission will decide whether to make it final.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

STAFF CONTACT: William P. Golden, Chicago Regional Office, 312-353-8156

FTC File No. 852 3212

[greatearth]

P. Leiner Nutritional Products Corp. D. 9173
Final consent 5/3/85

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 523-3830

FOR YOUR INFORMATION——June 12, 1985

The Federal Trade Commission has given final approval to the following consent agreements that it had provisionally accepted and placed on the public record for comments. They were all issued as final orders without modificiation.

- Associated Dry Goods Corp., one of the nation's leading retail companies. The consent agreement settles charges that the company failed to provide required Fair Credit Reporting Act notices to some consumers who were denied credit. The consent agreement was placed on the public record for comment Feb. 22 and issued M 7. (Docket No. C-3153)

- Descent Control Inc., manufacturer of safety devices for individuals working on or descending from tall buildings or heights. The consent agreement settles charges of false safety and performance claims. The consent agreement was placed on the public record for comment Feb. 5 and issued April 29. (Docket No. C-3152)

- P. Leiner Nutritional Products Corp., manufacturer of Octacol 4 capsules, which consist principally of wheat germ oil. The consent agreement settles charges of false and unsubstantiated advertising claims for the dietary supplement. The consent order was placed on the public record for comment Feb. 13 and issued May 3. (Docket No. 9173)

- Rush-Hampton Industries Inc., maker of the Ecologizer indoor air cleaner. The consent agreement settles charges of false, misleading and unsubstantiated ad claims that the system eliminated indoor air pollution. The consent order was placed on the public record for comment Feb. 5 and issued April 29. (Docket No. 9167)

- Young & Rubicam/Zemp Inc., advertising agency representing Rush-Hampton, makers of the Ecologizer air cleaner. The consent settles charges of false and unsubstantiated advertising claims for the product. The consent was placed on the public record for comment Feb. 5 and issued May 10. (Docket No. C-3154)

- Ward Corp., a Washington, D.C.-area home builder. The consent agreement settles a 1983 FTC complaint charging Ward with a substantial pattern of warranty violations in connection with its new homes. Under the consent order Ward will make repairs or pay homeowners for prior repairs that cost $500 or more to remedy. The consent order was placed on the public record for comment last Nov. 29 and issued April 5. (Docket No. 9166)

The Silver Group.

4/13/88

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
[illegible]

FOR YOUR INFORMATION.....................May 6, 1988

The Federal Trade Commission has given final approval to the following consent agreements that it had previously accepted and placed on the public record for comment:

- Multiple Listing Service Mid County Inc. The consent agreement settles charges that the Brooklyn, N.Y., company allegedly restrained price and service competition among residential real estate brokers. The agreement was placed on the public record December 30, 1987, and the final consent order was issued April 20, 1988. (Docket No. C-3227)

- Florence Multiple Listing Service Inc. The consent agreement settles charges that the Florence, S.C., company's membership restrictions and other policies restrained competition among real estate brokers. The agreement was issued for public comment on December 30, 1987, and issued April 20, 1988. (Docket No. C-3228)

- Medical Staff of Doctors' Hospital of Prince George's County, Md. The consent agreement settles charges that the medical staff of a hospital illegally tried to foreclose or limit competition by preventing the George Washington University Health Plan from opening a medical clinic in Prince George's County. The agreement was issued for public comment January 28, 1988, and the final consent order was issued April 14, 1988. (Docket No. C-3226)

- The Silver Group. The consent agreement settles charges that The Silver Group misrepresented the safety of its artificial tanning devices in claiming that its products do not pose the risk of skin aging or skin damage, including the risk of skin cancer. The agreement was placed on the public record January 27, 1988 and the final consent order was issued April 13, 1988. (Docket No. C-3225)

Commissioner Patricia P. Bailey did not participate in any of these matters.

Consent orders are for settlement purposes only and do not constitute admission of a law violation. When issued in final form, consent orders carry the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

[More]

A press release summarizing the complaint and consent agreement in each case was issued at the time of acceptance. Copies of the press releases and orders are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Brenda A. Mack, Office of Public Affairs,
202-326-2180

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FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: January 27, 1988

FTC CHARGES MARKETER OF SUNTANNING DEVICES FALSELY CLAIMED ITS PRODUCTS DO NOT INCREASE THE RISK OF SKIN CANCER OR AGING; CONSENT AGREEMENT PROHIBITS FALSE AND UNSUBSTANTIATED CLAIMS

The Federal Trade Commission has charged a major marketer of artificial tanning devices with falsely claiming that its products do not pose the risk of skin aging or skin damage, including the risk of skin cancer. A consent agreement issued today for public comment prohibits The Silver Group Inc. from misrepresenting the safety of its products.

Silver sells tanning devices and related products, including tanning beds, facial units, and overhead lamp systems. The company's tanning devices use lamps emitting ultraviolet radiation to cause tanning of the user's skin.

According to the FTC staff, Silver markets its products — primarily under the trade name Silver Solarium — to tanning salons, health clubs, and beauty parlors as well as to individuals. Silver advertises its products in national magazines, such as Gentleman's Quarterly, Playboy, and Shape, and in fitness and beauty salon publications and airline in-flight magazines.

According to an FTC complaint issued with the consent agreement, in its ads and in literature Silver made claims such as: "New way to tan indoors with absolutely no harmful side effects associated with the sun." Other ads claimed "Safer than the sun!" and "Absolutely no burning, no drying and no sun damage," the complaint stated.

The complaint charged that these claims are false. In addition, the complaint charged, Silver falsely claimed it had reliable scientific evidence for its claims.

In fact, according to the complaint, Silver's products cannot be used without the risk of any harmful side effect associated with the sun, and their use can increase the risk of developing skin cancer and can contribute to skin aging.

The consent agreement prohibits the company from misrepresenting, directly or by implication, that its devices do not pose for users a risk of any harmful side effect associated with sun exposure.

In addition, the consent agreement requires the company to have reliable and competent scientific evidence for any health or safety claim it makes in any advertisement.

For one year after the consent is made final, Silver must include the following statement in any ads and promotional materials for its tanning devices, "NOTICE — Read the mandatory FDA warning label found on every tanning machine for important information on potential eye injury, skin cancer, skin aging and photosensitive reactions." After the first year, the company must include that statement in any ads that claim its tanning device is safe or safer than other devices or other methods of tanning, or that the device has health benefits.

(More)

Silver is based in San Francisco and is a subsidiary of Silver Gruppen of Denmark.

The consent agreement is scheduled to appear in the Federal Register today. It will be subject to public comment until March 28, after which the Commission will decide whether to make it final.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

STAFF CONTACT: C. Lee Peeler, Bureau of Consumer Protection, 202-326-3090

FTC File No. 882 3013

l[SilverGrp]

Philip Goutell ([illegible]) stipulated permanent injunction 4/12/88 S.D.N.Y.

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: April 15, 1988

MAIL-ORDER COMPANY OFFICER TO PAY $300,000, AGREES NOT TO VIOLATE MAIL-ORDER RULE OR MISREPRESENT MERCHANDISE, UNDER COURT SETTLEMENT

The Federal Trade Commission today announced that Philip Goutell, president of two mail-order companies, has agreed to pay $300,000 in civil penalties to settle charges that he violated the FTC's mail-order rule. Under the court-approved settlement, he also agreed to a permanent injunction that settles charges that he misrepresented the products he sold.

The stipulated permanent injunction settles a government suit against Goutell and two companies, Frank E. Bush Inc. and Conceptual Trends Inc. Seven other mail-order companies and three individuals were also named in the original FTC suit. They settled the charges against them in August 1987.

In January 1985, the U.S. Attorney for the Southern District of New York, on behalf of the FTC, charged in a court complaint that the defendants misrepresented their nationally advertised mail-order products, ranging from copper cookware to "sex pills", and also violated the FTC's mail-order rule.

Goutell and the two companies agreed not to misrepresent any product they sell through the mail in the future, including copper cookware, china dishes, kitchen canisters, binoculars or field glasses, air conditioners or air coolers, kerosene lamps, or pills to remedy male impotence. In its 1985 complaint, the government had charged that the companies made "false or misleading claims" about these products.

The companies and individuals further agreed not to violate the FTC's mail-order rule in the future. The complaint had charged that the companies failed to deliver merchandise on time, did not properly notify or offer consumers the right to cancel, and "in numerous instances" did not cancel orders or make prompt refunds to consumers.

The Department of Justice filed the settlement in the U.S. District Court for the Southern District of New York, in New York City, at the FTC's request.

This stipulated permanent injunction is for settlement purposes only and does not constitute an admission by the individual or companies that they violated the law. It has the force of law.

Copies of the stipulated permanent injunction are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181
STAFF CONTACT: Joel Winston, Bureau of Consumer Protection, 202-326-3153

(Civil Action No. 85 Civ. 130 (TPG)) (FTC File No. 832 3014)
(Goutell)

Figgie International Inc. Complaint for redress 7/88
C.DG

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: July 19, 1988

FTC ASKS COURT TO ORDER FIGGIE INTERNATIONAL TO PAY REDRESS TO CONSUMERS WHO BOUGHT ITS HEAT DETECTORS

The Federal Trade Commission has asked a federal district court to order Figgie International Inc. to pay redress to consumers who bought Vanguard brand heat detectors based on the company's false claims that the heat detectors give consumers sufficient warning to escape from most residential fires.

The Commission issued an administrative complaint in 1983, challenging Figgie's claims, and an administrative law judge upheld the complaint.

In 1986, the Commission ruled that the claims were deceptive, saying "heat detectors often provide no advance warning." In fact, the Commission found that the evidence showed that "smoke detectors provide significantly earlier warning of potentially dangerous conditions resulting from a residential fire than do heat detectors."

A federal court of appeals upheld the Commission's order in 1987.

According to the Commission's complaint filed in court yesterday, Figgie deceptively claimed that:

-- Vanguard heat detectors provide the necessary warning to allow consumers time to escape from most residential fires; and

-- the Vanguard combined system of heat detectors and smoke detectors provides significantly greater fire warning than smoke detectors alone because heat detectors give earlier warning of hot, flaming fires.

Consumers "incurred substantial losses" of at least $2.9 million when they purchased Vanguard heat and smoke detectors based on these deceptive claims, the complaint charges. The Commission estimated in its earlier decision that most Vanguard combined systems cost between $600 and $1000.

(More)

The Commission asked the court to order Figgie to pay redress to consumers who purchased residential fire alarm systems consisting of heat detectors alone or in combination with smoke detectors between May 18, 1980, and July 20, 1987.

The Commission filed its complaint in the U.S. District Court for the Central District of California, in Los Angeles. Figgie is based in Richmond, Va.

Copies of the FTC's complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181

STAFF CONTACT: Ann Guler, Los Angeles Regional Office, 213-209-7890

(FTC Docket No. 9166)

(figge)

R. J. Reynolds Tobacco Co.: Complaint issued 6/16/86

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: April 11, 1988

FTC REVERSES ADMINISTRATIVE LAW JUDGE'S DECISION TO DISMISS R. J. REYNOLDS CASE; REMANDS CASE TO ALJ

The Federal Trade Commission reversed a decision of an administrative law judge (ALJ) that had dismissed the FTC complaint against the R. J. Reynolds Tobacco Co., and remanded the case to the ALJ for further action. In its decision, the Commission stated that the judge erred when he granted R.J. Reynolds' motion to dismiss the complaint on the ground that it was not subject to the Commission's jurisdiction and when "he ruled that further opportunity to discover and present facts relating to jurisdiction was not permitted." The complaint alleges deception by Reynolds in the "dissemination of an advertisement entitled 'Of Cigarettes and Science'," dealing with the relationship between smoking and health. The vote to reverse the ALJ's decision and remand the matter was 4-1, with FTC Chairman Daniel Oliver dissenting.

In June 1986 the FTC issued a complaint charging that R. J. Reynolds' "Of Cigarettes and Science" was an advertisement that misrepresented the purpose and results of a scientific study. The study was known as the Multiple Risk Factor Intervention Trial, or MR FIT. The complaint charged that "Of Cigarettes and Science" made claims about the MR FIT study that were false or misleading, including making false claims that the study provided credible scientific evidence that smoking is not as hazardous as the public or the reader has been led to believe. The complaint also charged that it was deceptive because it failed to disclose certain information about the study's findings.

R. J. Reynolds filed a motion to dismiss the FTC complaint on the grounds that "Of Cigarettes and Science" was an editorial fully protected by the First Amendment and therefore could not be regulated by the FTC. In August 1986 ALJ Montgomery K. Hyun dismissed the case, concluding the text of "Of Cigarettes and Science" was noncommercial speech that was fully protected by the First Amendment and therefore was beyond the FTC's jurisdiction.

However, according to the Commission decision, which was written by Commissioner Andrew J. Strenio, Jr., "viewed in light of the allegations contained in the complaint, we conclude that the ALJ erred when he granted respondent's motion to dismiss at this stage of the proceeding."

The Commission stated in its decision, "We agree with the parties and the ALJ that unless the Reynolds advertisement can be classified as commercial speech, it is not subject to the Commission's jurisdiction." According to the Commission, however, "the ALJ was required to consider the various 'messages, means, and motives' of the advertisement" in determining whether it is commercial speech.

The Commission concluded that, "Accepting the allegations of the complaint concerning jurisdiction as true for purposes of this appeal," — the standard legal approach — "the content of the Reynolds advertisement includes words and messages that are characteristic of commercial speech." The Commission opinion discusses

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whether "Of Cigarettes and Science" constitutes commercial speech in light of the complaint allegations about jurisdiction. The following characteristics that the Supreme Court has identified as relevant to determining whether speech is commercial are stated in the Commission decision:

- The content of "the advertisement refers to a specific product, cigarettes."
- The content of "the advertisement discusses an important product attribute — the alleged connection between smoking and heart disease." "A message that addresses health concerns that may be faced by purchasers or potential purchasers of the speaker's product may constitute commercial speech."
- "The 'means' used to disseminate the Reynolds ad — paid-for advertising — is characteristic of commercial speech."
- Reynolds is in the business of selling cigarettes. "It is not unreasonable to infer that Reynolds, as a seller of cigarettes, had a direct, sales-related motive for disseminating the 'Of Cigarettes and Science' advertisement." "[E]conomic motivation also may be indicative of commercial speech.".

The decision stated, "It should be clear, however, that the Commission makes no final determination of jurisdiction." According to the Commission, a final determination at this stage of the proceeding would be premature. Instead, the Commission remanded the case to the ALJ "for the purpose of determining whether the facts as applied to appropriate legal standards support the existence of jurisdiction."

The Commission stated, "If the ALJ determines that additional evidence is needed to make a final determination on jurisdiction, he shall permit further opportunity to develop and present evidence on the issue," although the Commission did not conclude that presentation of additional evidence necessarily was required. The Commission rejected Reynolds' contention that consideration of extrinsic evidence, which is evidence other than the statement itself, was irrelevant to determining jurisdiction or that consideration of such evidence would violate the First Amendment.

In the decision, the Commission reaffirmed that the protections the First Amendment affords "are of fundamental importance to a democratic society." The Commission noted, however, that the Constitution "accords different degrees of protection based upon the type of speech at issue." According to the decision, regulation of fully protected speech "generally is limited to reasonable time, place and manner restrictions," but commercial speech "can be regulated on the basis of its content." The Commission stated, "The more limited protection accorded commercial speech permits the FTC to act when necessary to challenge false or deceptive advertising."

In a dissenting statement, Chairman Daniel Oliver stated that he would have affirmed the ALJ and dismissed the complaint. He cited decisions of the Supreme Court that have concluded that corporations have the full protection of the First Amendment for their "direct comments on public issues." In his view, the statement by R.J. Reynolds was a direct comment in which the company "questioned the objectivity of the scientists who examine the issue of smoking and health." He stated that, "If the editorial is deceptive, or not believable, or runs counter to other information on the health question

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that the public is aware of, consumers are free to reject the message in the editorial. But it is critical for First Amendment purposes that the public, and not the government, decide the answer to this question."

Chairman Oliver also disagreed with the decision to remand the case for additional discovery. He noted that much of the evidence the majority suggested would be relevant was simply background information that was not needed. He disagreed with the majority's conclusion that evidence of Reynold's motive was relevant, stating that "the Supreme Court has never looked to the subjective intent of the speaker" in deciding whether speech was fully protected or commercial.

Copies of the Commission decision are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

FTC File D.9206

i[RJRDec]

General Nutrition Corp. Provisional Consent 3/14/88

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: June 13, 1988

GENERAL NUTRITION CORP. TO PAY $600,000 TO SETTLE CHARGES IT MADE FALSE AND MISLEADING ADVERTISING CLAIMS ABOUT FOOD SUPPLEMENTS

Consent Agreement Settles 1984 Charges About Healthy Greens and Additional Charges About Six Other Food Supplements

The Federal Trade Commission today announced that General Nutrition Corp. Inc. (GNC) has signed a consent agreement settling 1984 FTC charges that it made *false* and unsubstantiated claims that a diet supplement, "Healthy Greens," was effective in reducing the risk of cancer. The consent agreement also settles additional charges from a separate investigation that the company falsely claimed six other food supplements would promote weight loss and muscle growth or retard aging.

The consent agreement requires that, in lieu of consumer redress, GNC pay a total of $600,000 for research in nutrition, obesity, or physical fitness. The money is to be divided equally among the American Diabetes Association, the American Cancer Society, and the American Heart Association. The consent agreement, which has been placed on the public record for comment, also prohibits GNC from making false and unsubstantiated claims about its products.

The vote to issue the consent agreement and an amended complaint was 3-2, with Chairman Daniel Oliver and Commissioner Mary L. Azcuenaga dissenting.

GNC is a nationwide chain of retail outlets that sell a wide range of health food products, including vitamins and mineral supplements, weight loss products, and cosmetics. In 1986 GNC had sales of more than $300 million through approximately 1,100 stores, most of which are called General Nutrition Centers. GNC is based in Pittsburgh.

Following the Commission's 1984 complaint charging that GNC made false claims about Healthy Greens, an administrative law judge (ALJ) conducted a hearing on the allegations. In 1986 the ALJ, Montgomery K. Hyun, issued an order prohibiting GNC from making "false and unsubstantiated advertising claims in the future for any product marketed for its ability to prevent or reduce the risk of any disease in humans." Both the company and the FTC staff appealed the ALJ's decision to the Commission. The matter was withdrawn from litigation for the negotiations that led to this consent agreement. "Healthy Greens," which GNC no longer markets, were sold in the form of pills and contained dehydrated vegetables and some vitamins and minerals.

The amended complaint issued with today's consent also includes charges that GNC made false claims that six food supplements would enable users to lose weight, retard aging, or build muscle. The six food supplements are: "Challenge Growth and Training Vita-Pak," "Challenge Free Form Amino Acids," "Life Expander Growth Hormone Releaser, "24 Hour Diet Plan," "L-Arginine," and "L-Ornithine."

The consent agreement prohibits GNC from falsely claiming that government reports support the use of products such as Healthy Greens to reduce cancer risk. The consent also prohibits GNC from misrepresenting any scientific test with respect to any product's ability to affect disease.

The amended complaint also charges that GNC falsely claimed it had a reasonable basis for its claims about Healthy Greens and the six food supplements. The consent agreement prohibits GNC from making disease-related claims for any product without having competent and reliable scientific evidence.

However, the consent agreement provides that GNC will not be liable for claims on package labels or inserts for products sold in its stores if they are: manufactured and distributed by a third party without input from GNC; generally available at competing retail outlets; not identified with GNC in any way, such as with its logo; and which GNC does not advertise or promote.

Commissioner Mary L. Azcuenaga said she dissented from accepting the proposed consent order because it "leaves GNC free to sell products that it knows are deceptively labeled." She stated, "I believe that the order should hold GNC liable if it knows that the packaging of these products contains unsubstantiated claims."

The FTC's Bureau of Consumer Protection brought the original charges involving Healthy Greens; the Chicago Regional Office handled the investigation of the other food supplements.

The consent will be subject to public comment for 60 days, until Aug. 12, after which the Commission will decide whether to make it final. Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580. A Federal Register notice is scheduled to be published today.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

STAFF CONTACT: Robert C. Cheek, Bureau of Consumer Protection, 202-326-3045 (Healthy Greens)

Timothy T. Hughes, Chicago Regional Office, 312-353-4423 (six food supplements)

FTC File No. D 9175

[GNCconsent]

General Nutrition Corp. Final consent 2/2/89

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

OFFICE OF PUBLIC AFFAIRS
(202) 326-2180

FOR YOUR INFORMATION............ February 13, 1989

The Federal Trade Commission has given final approval to a consent order with General Nutrition Corp. Inc. (GNC). The order requires GNC to pay a total of $600,000 for research, and prohibits GNC from making false and unsubstantiated claims about its products.

The consent order issued for public comment in June 1988, settles 1984 FTC charges that GNC made false and unsubstantiated claims that its diet supplement, "Healthy Greens," was effective in reducing the risk of cancer. The consent order also settles additional charges from a separate investigation that the company falsely claimed six other food supplements would promote weight loss and muscle growth or retard aging.

The consent order requires that GNC divide the $600,000 equally among the American Diabetes Association, the American Cancer Society, and the American Heart Association for research in nutrition, obesity, or physical fitness.

A consent order is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

The vote to issue the order was 3-1, with Commissioner Mary L. Azcuenaga dissenting and Commissioner Margot Machol not participating. In a separate statement, Commissioner Azcuenaga stated that she dissented "because the order leaves GNC free to sell products that it knows are deceptively labeled."

Copies of the Commission's order, complaint and the dissenting statement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Brenda Mack, Office of Public Affairs,
202-326-2182

STAFF CONTACT: Robert C. Cheek, Bureau of Consumer Protection,
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C. Stephen Baker, Chicago Regional Office,
312-353-4423

[GNCORD]

General Nutrition, Inc. D. 9175
I.D. [illegible]

FTC

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: March 3, 1986

FTC JUDGE RULES ADS CLAIMING DIET SUPPLEMENT REDUCED CANCER RISKS WERE FALSE; UPHOLDS FTC CHARGES AGAINST GENERAL NUTRITION INC.

General Nutrition Inc.'s advertisements claiming that its dietary supplement "Healthy Greens" reduced the chances of contracting cancer were deliberately false, misleading and deceptive, a Federal Trade Commission administrative law judge has ruled. The judge issued an order prohibiting the company from making "false and unsubstantiated advertising claims in the future for any product marketed for its ability to prevent or reduce the risk of any disease in humans."

Judge Montgomery K. Hyun's ruling upholds a March 1984 FTC complaint charging that General Nutrition's ads for Healthy Greens were deceptive. Healthy Greens are pills containing dehydrated vegetables and some vitamins and minerals. General Nutrition is a major seller of vitamins and food supplement products and had 1983 sales of more than $350 million. The company sold Healthy Greens through a subsidiary that operates about 1100 retail health food and vitamin stores nationwide.

According to Judge Hyun, General Nutrition's use of false, misleading and deceptive claims could have misled the public into buying Healthy Greens. He concluded that the company's actions were unfair and deceptive and violated the FTC Act. The order the judge issued prohibits the company from:

- claiming that the National Academy of Sciences/National Research Council or other research group found that use of Healthy Greens or other similar products reduces the risk of cancer in humans, unless the claim is true;
- misrepresenting the purpose or conclusions of any scientific study with respect to any product's ability to cure, prevent or reduce the risk of any disease in humans; or
- making any claims about a supplement's ability to reduce the risk of any disease unless it has, at the time the claim is made, competent and reliable scientific or medical evidence including at least one well-controlled human clinical trial which supports such a claim.

According to Judge Hyun, the order "is intended to ensure that future advertising claims will not mislead consumers into believing that a particular product attribute enjoys any greater support or authority within the scientific community than it enjoys in fact."

General Nutrition based some of its ad claims about Healthy Greens' ability to reduce the incidence of cancer on a 1982 National Academy of Sciences/National Research Council report, titled "Diet, Nutrition and Cancer." However, Judge Hyun concluded that the report did not support General Nutrition's claims and that those claims were therefore false. According to the judge, the report recommended that people include in their diet vegetables, fruits and whole grain cereal products, which have been shown to be associated with a lower cancer risk.

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But, the judge wrote, the report "specifically states that its recommendations apply only to foods and not to nutrients or supplements." Finally, he concluded, General Nutrition "knew that the use of Healthy Greens tablets was not supported by the report or by the other prior substantiation documents in its possession."

According to the FTC complaint, one ad for Healthy Greens claims: "By taking Healthy Greens you may reduce your chances of getting cancer." Another states, "And judging from the NRC study for the National Cancer Institute [Healthy Greens is] just possibly your best hedge against cancer."

According to Judge Hyun, General Nutrition represented in its ads, through references to the National Research Council report and to other scientific research, that it possessed evidence generally accepted by the scientific community as proving its claims. However, he concluded, nowhere does the report mention dehydrated vegetables as providing any benefits against cancer in humans. In addition, he wrote, the company's "so-called substantiation material" that relates to other scientific research does not constitute competent and reliable scientific evidence.

In addition, General Nutrition claimed that vitamin E, which Healthy Greens contains, plays an important role in reducing the risk of cancer. In fact, according to Judge Hyun, "research has not demonstrated that vitamin E or any other nutrient plays any role in reducing the risk of cancer in humans, much less an important role." Therefore, he concluded, those claims were false.

Judge Hyun concluded that consumer injury from General Nutrition's ads for Healthy Greens was significant. He found that the principal injury was the economic harm to the consumer resulting from repeated purchase of an ineffective product. However, according to Judge Hyun, there were also health risks to consumers who took Healthy Greens. Those who took the tablets instead of including whole vegetables in their diet, as the National Research Council recommended, may have lost the benefits to be derived from following the dietary recommendations. He also found that consumers faced health risks because the diet supplement had some potential to cause toxicity or overdosing of some vitamins.

The judge concluded that General Nutrition's violations were deliberate. He said that the company claimed its product was carefully developed and supported by scientifically-acceptable evidence when it was not. In fact, according to Judge Hyun, General Nutrition "allocated scant efforts to develop Healthy Greens." merely copying another company's product and doing "next to nothing" to determine its effectiveness.

In its 1983 FTC policy statement regarding advertising substantiation, the Commission said that advertisers must possess and rely upon a reasonable basis for its claims. Judge Hyun concluded that General Nutrition had not substantiated its claims for Healthy Greens and therefore did not possess a reasonable basis for them.

Finally, according to the judge, "There is also reason to conclude that General Nutrition's unconscionable, false and misleading advertising found in this case is not an isolated incident but in fact is a part of a continuing pattern." He pointed out that the record contains 14 consent agreements the company entered into with the U.S. Postal Service and one with California to settle charges of false advertising for food supplements.

General Nutrition, which is based in Pittsburgh, no longer markets Healthy Greens. The company sold about 24,000 bottles at prices ranging from $8.99 to $12.99.

Copies of the initial decision are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Public Affairs Office 202-523-1891
[HealthyG2]

General Nutrition - Complaint

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: March 28, 1984

FTC CHALLENGES ADS CLAIMING DIET SUPPLEMENT "HEALTHY GREENS" REDUCES CHANCES OF CANCER

General Nutrition Inc.'s false and unsubstantiated advertising claims promoting its dietary supplement "Healthy Greens" are deceptive, the Federal Trade Commission charged in a complaint today. General Nutrition represented deceptively that Healthy Greens is associated with reduced incidence of cancer in humans, and that a National Academy of Sciences' report supports that claim, the FTC alleged.

Healthy Greens are pills containing dehydrated vegetables and some vitamins and minerals. General Nutrition sells Healthy Greens through a subsidiary which operates approximately 1050 retail health food and vitamin stores nationwide. According to Standard and Poor's, General Nutrition had annual sales in 1982 of more than $355 million.

General Nutrition bases some of its ad claims about Healthy Greens' ability to reduce the incidence of cancer on a 1982 National Academy of Sciences' National Research Council report. The Commission alleges, however, that the report does not support those claims. General Nutrition also allegedly falsely represents that Vitamin E plays an important role in reducing the risk of cancer.

In July 1983, the FTC issued a complaint against a similar product about which similar claims were made. The Commission charged Pharmtech Research Inc. with making deceptive advertising claims that its dietary supplement Daily Greens was associated with a reduction in the incidence of cancer in humans. In November 1983, the Commission obtained a preliminary injunction in federal court prohibiting such claims. In February, the Commission accepted a consent order with Pharmtech which prohibits the company from making those deceptive claims.

According to today's complaint, one ad for Healthy Greens claims: "By taking Healthy Greens you may reduce your chances of getting cancer." Another states, "And judging from the NRC study for the National Cancer Institute [Healthy Greens is] just possibly your best hedge against cancer." A third ad claims, "The evidence is coming in, and it all points to Healthy Greens as being an important ingredient to your well-being."

The complaint charged General Nutrition deceptively claims to have a reasonable basis to support its representation that Healthy Greens is associated with a reduction in the incidence of some human cancers.

If an administrative law judge upholds the charges, the FTC could issue an order prohibiting General Nutrition from representing, contrary to fact, that the 1982 NAS Diet, Nutrition and Cancer report supports the claims that use of such a product is associated with a reduction in the incidence of any type of cancer. The order could also prohibit misrepresenting any scientific test or research article with respect to its product's ability to cure, prevent or reduce the risk of disease in humans. The order could further prohibit General Nutrition from making claims concerning the health benefit of any product marketed for its ability to cure, prevent or reduce the risk of disease unless it relies on competent scientific evidence.

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General Nutrition's headquarters are in Pittsburgh.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs,
202-523-1891

STAFF CONTACT: Andrew Sacks, Bureau of Consumer Protection,
202-376-8648

File No. 832 3249

[HealthyG]

Kingsbridge Media + Marketing Inc. Refunds
(Dream Away)

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: October 17, 1988

FTC ANNOUNCES $1,040,000 PAID IN REFUNDS TO "DREAM AWAY" CUSTOMERS; SEEKS ADDITIONAL PURCHASERS

The Federal Trade Commission announced that $1.04 million has been sent in refund checks to purchasers of "Dream Away" diet pills. However, the Commission is continuing to search for additional purchasers who may not have submitted an application for refunds.

In June the FTC announced that the maker of "Dream Away" and "Advanced Dream Away" had turned over $1.1 million, which the Commission is using to pay refunds to purchasers.

The product was advertised on cable television from 1984 until January 1988, with such claims as "Just take Dream Away before going to bed. You will wake up the next morning slimmer, trimmer, and looking better than you did before." The Commission filed a complaint in federal court in January charging that the product does not cause weight loss in a short period of time, while sleeping, or at all.

The Commission said that a total of about $102,000 was sent to 3,000 Dream Away purchasers who sent in valid claims. In addition, checks for $19.95 -- the price of one bottle -- were sent to approximately 47,000 names found on the company's customer list. The Commission is encouraging the people on that list who may have purchased more than one bottle, or purchasers who have not previously submitted claims to write to:

Redress Offer
Dream Away Settlement Fund
Federal Trade Commission
P.O. Box 990
Corte Madera, CA 94925

Consumers should include proof of purchase, such as a cancelled check or credit slip, to insure that they are included. The deadline is December 1. Checks for additional refunds will be mailed in mid-February 1989.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181
STAFF CONTACT: Nancy Warder, Bureau of Consumer Protection, 202-326-3048

(DreamRed)

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: June 22, 1988

FTC BEGINS $1.1 MILLION REDRESS PROGRAM FOR CONSUMERS WHO BOUGHT "DREAM AWAY" DIET PILLS

The Federal Trade Commission today announced that it has established a program to refund money to consumers who bought "Dream Away" and "Advanced Dream Away" diet pills. The marketer of the pills has turned over $1.1 million dollars for the redress fund.

Consumers who think they are eligible for refunds should write to:

Redress Offer
Dreamaway Settlement Fund
Federal Trade Commission
P.O. Box 990
Corte Madera, Calif. 94925

Consumers should include proof of purchase, such as a cancelled check or credit slip, to insure that they are included in the fund. The deadline is August 22, 1988. The FTC staff estimates that the refunds will be mailed during November 1988.

The product was advertised on cable television from 1984 until January 1988, with such claims as "Just take Dream Away before going to bed. You will wake up the next morning slimmer, trimmer, and looking better than you did before." The product cost $19.95 for a 21-day supply of pills consisting of small amounts of amino acids found in abundance in ordinary diets.

The Commission's complaint, filed in federal court in January, charged that, in fact, the product does not cause weight loss at all, while sleeping, or in a short period of time. Dream Away also does not cause weight loss without dieting or exercising and does not contribute to the weight loss effects of dieting or exercising, the complaint alleged.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181
STAFF CONTACT: Nancy Warder, Bureau of Consumer Protection, 202-326-3048

(dreamawa)

Performance Nutrition & Marketing Inc. (Dream Away) Final Judgment [illegible] 6/7/88 D. Ariz.

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: June 6, 1988

FTC ANNOUNCES "DREAM AWAY" DIET PILL MARKETER AGREES TO DISGORGE $1.1 MILLION IN SETTLEMENT OF FALSE ADVERTISING CASE

The Federal Trade Commission announced today that the marketer of Dream Away diet pills has agreed to disgorge $1.1 million because of false advertising claims that taking Dream Away would enable consumers to lose weight while sleeping and without exercising or dieting. The settlement will be filed in federal court today.

The Commission filed a complaint in U.S. District Court for the District of Arizona, in Phoenix, in January, charging four companies and three individuals with false, deceptive and unsubstantiated advertising. At that time, the court issued a temporary restraining order putting an immediate stop to the ad claims and froze the assets of the companies and individuals.

The defendants made such claims for Dream Away and Advanced Dream Away as "Just take Dream Away before going to bed. You will wake up the next morning slimmer, trimmer, and looking better than you did before." They charged $19.95 for a 21-day supply of pills consisting of small amounts of amino acids found in abundance in ordinary diets.

The Commission's complaint charged that, in fact, the product does not cause weight loss at all, while sleeping, or in a short period of time. Dream Away also does not cause weight loss without dieting or exercising, and does not contribute to the weight loss effects of dieting or exercising, the complaint alleged.

Under the settlement to be filed today, Nutri Marketing, which sells the pills, has agreed to put $1,100,000 into an escrow account. The Commission may use this money to pay direct refunds to consumers who bought Dream Away and Advanced Dream Away. If Nutri Marketing defaults on the payment or is placed in bankruptcy, the remaining defendants have agreed to make the payment.

In addition, under the final judgment and order, the defendants have agreed not to:

- misrepresent the performance, efficacy, or safety of any food, drug, or device;
- make any representation concerning the performance, efficacy, or safety of any food, drug, or device, unless they have a reasonable basis to substantiate the claim; and
- represent that Dream Away, Advanced Dream Away, or any other comparable amino acid product causes, or substantially contributes to, a loss of weight.

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In addition, the defendants agreed to disclose prominently that dieting and/or exercise is required in order to lose weight, in any ads for weight control or reduction products, programs or services.

Consumers who think they are eligible for refunds should contact the FTC by writing to Nancy Warder. The Commission staff said that it already has a list of 50,000 past customers, but that many more are probably eligible.

The final judgment and order names Kingsbridge Media & Marketing Inc. and Frank E. Robinson, both of Van Nuys, Calif.; and Highcliff Inc., Nutri Marketing, Vista Advertising, Mel Korey and Steve Korey, all of Scottsdale, Ariz.

This final judgment and order is for settlement purposes only and does not constitute an admission by the defendants or a ruling by the court that the law has been violated. Consent judgments have the force of law.

Copies of the final judgment and order are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-326-2181

STAFF CONTACT: Lee Peeler, Bureau of Consumer Protection,
202-326-3090

(Civil No. CIV-88-0003 PHX EHC)

(FTC File No. X88 0002)

(DreamAway2)

Dream Away - Kingsbridge Media + Marketing Inc.

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: January 11, 1988

FTC CHARGES THAT WEIGHT LOSS CLAIMS FOR "DREAM AWAY" DIET PILLS ARE FALSE, SEEKS INJUNCTION, CONSUMER REDRESS

The Federal Trade Commission has charged that advertising claims that Dream Away diet pills will cause users to lose weight while sleeping and without exercise or diets are false and deceptive. A federal district court has issued a temporary restraining order putting an immediate stop to such claims and froze the assets of four companies and three individuals.

The Commission's complaint charges the defendants with making false advertising claims. The complaint asks the U.S. District Court for the District of Arizona, in Phoenix, to issue preliminary and permanent injunctions and order them to pay consumer redress.

The complaint alleges that, in television ads and in promotional materials, the defendants made such claims for Dream Away and Advanced Dream Away as: "Just take Dream Away before going to bed. You will wake up the next morning slimmer, trimmer, and looking better than you did before."

The complaint charges, however, that Dream Away:

- does not cause a loss of weight or fat at all, while sleeping, or in a short period of time; and
- does not cause weight loss without dieting or exercise and does not contribute to the weight loss effects of dieting or exercising.

In addition, the complaint alleges that the defendants did not have a reasonable basis for the advertising and promotional claims they made.

As a result of these false and deceptive claims, consumers have suffered, and continue to suffer, "substantial injury," while the defendants "have enjoyed, and continue to enjoy, substantial monetary gains," according to the complaint.

The complaint names Kingsbridge Media & Marketing Inc. and Frank E. Robinson, both of Van Nuys, Calif.; and Highcliff Inc., Nutri Marketing, Vista Advertising, Mel Korey and Steve Korey, all of Scottsdale, Ariz.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-326-2181
STAFF CONTACT:	Joel Winston, Bureau of Consumer Protection, 202-326-3153

(Civil Action No. CIV 88-003 PHX EHC

(FTC File No. 872 3141) (DreamAway)

North American Philips Corp. final decision 10/24/88
(water cleaner) D. 9209

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: November 1, 1988

FTC ACCEPTS ADMINISTRATIVE LAW JUDGE'S FINDING THAT NORELCO FAILED TO DISCLOSE WATER CLEANER ADDS POTENTIALLY HAZARDOUS CHEMICAL TO WATER

The Federal Trade Commission has accepted an administrative law judge's finding that Norelco falsely advertised that its Clean Water Machine would make tap water clean or cleaner, when it knew that the machine added a potentially hazardous chemical to the water. The Commission put into effect Administrative Law Judge James P. Timony's order requiring the company not to misrepresent the performance of the Clean Water Machine or any other electric-powered consumer appliance.

A 1987 FTC complaint charged North American Philips Corp., Norelco's parent company, with false advertising. The Commission and the judge's initial decision, issued September 19, 1988, upheld that complaint.

The decision found that the glue used in the product's replaceable filter cartridge contained methylene chloride, a suspected carcinogen, which leached into the water passing through the machine. Although Norelco was notified of the problem in 1982, it continued to sell the filters, called G1 filters, until 1986. The filters remained available in stores longer than that, with an FTC employee purchasing one in the Washington, D.C., area in August 1987.

"That Norelco exposed consumers to methylene chloride for three years knowing that the chemical had been linked to cancer demonstrates disregard for the welfare of its consumers and a 'blatant and utter disregard' for the law," according to the decision.

The judge found that Norelco's claims that the Clean Water Machine helped remove organic chemicals from the water it was treating were false, because the machine added far more chemicals than it removed. For the same reason, Norelco's claims to make water clean or cleaner were false.

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The claim that independent laboratory tests proved that the Clean Water Machine made tap water clean was also found to be false. In addition, ads that Norelco had implied a reasonable basis for the performance claims were false and unsubstantiated "because of the methylene chloride problem."

"Consumers paid $50 for a product that they thought would promote good health, only to find that it might pose an additional potential hazard," according to the decision.

After learning of the filter problem, "Norelco allowed unsuspecting consumers to buy and use the remaining 214,000 contaminated filters that remained in its warehouse and the thousands still available on the retail shelf and in Norelco's own ... stores," according to the decision. In 1986, after being contacted by the FTC and other governmental agencies, Norelco decided to notify consumers about the problem and offer a replacement filter. "Although ... [the company] sold more than 248,000 Clean Water Machines, it sent notices only to its trade customers and to 19,188 consumers."

Under the order, Norelco cannot make the challenged false claims for the Clean Water Machine or any other product that treats water, and cannot misrepresent any test or study of its products. In addition, it must have substantiation for any performance claims it makes for any electric-powered consumer appliance. Such appliances include hair dryers, makeup mirrors, coffee makers, and razors.

North American Philips is one of the world's largest electronics companies, and produces and sells consumer and commercial lighting and electrical products. Its Norelco Consumer Products Division is a leader in the electric housewares industry. It is based in New York City.

The Commission adopted Judge Timony's decision and voted unanimously to issue the judge's order. Since neither respondent nor complaint counsel filed an appeal, the order becomes effective automatically.

Copies of the Commission's final order and the administrative law judge's decision are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W. Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502

# # #

MEDIA CONTACT: Brenda A. Mack, Office of Public Affairs, 202-326-2180

(Docket No.9209)

(Norelco2)

North American Philips Corp
(water filter) I.D. 8/30/88 Issued 9/19/88

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: September 19, 1988

FTC JUDGE RULES NORELCO FAILED TO DISCLOSE WATER CLEANER ADDS POTENTIALLY HAZARDOUS CHEMICAL TO WATER; ORDERS COMPANY NOT TO MISREPRESENT ANY PRODUCT'S PERFORMANCE

A Federal Trade Commission judge has ruled that Norelco falsely advertised that its Clean Water Machine would make tap water clean or cleaner, when it knew that the machine added a potentially hazardous chemical to the water. The judge, calling the violations "serious, deliberate and egregious," ordered the company not to misrepresent the performance of the Clean Water Machine or any other electric-powered consumer appliance.

Judge James P. Timony's initial decision and order uphold a 1987 FTC complaint charging North American Philips Corp., Norelco's parent company, with false advertising.

Judge Timony found that the glue used in the product's replaceable filter cartridge contained methylene chloride, a suspected carcinogen, which leached into the water passing through the machine. Although Norelco was notified of the problem in 1982, it continued to sell the filters, called G1 filters, until 1986. The filters remained available in stores longer than that, with an FTC employee purchasing one in the Washington, D.C., area in August 1987.

"That Norelco exposed consumers to methylene chloride for three years knowing that the chemical had been linked to cancer demonstrates disregard for the welfare of its consumers and a 'blatant and utter disregard' for the law," the judge wrote.

Norelco's claims that the Clean Water Machine helped remove organic chemicals from the water it was treating were false, because it added far more chemicals than it removed, according to the decision. For the same reason, its claims to make water clean or cleaner were false.

In addition, the claim that independent laboratory tests proved that the Clean Water Machine made tap water clean was also false. "Since the Machine, in fact, did not make the water clean or cleaner, tests could not have proven that it did," the judge

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found. Advertising that implied a reasonable basis for the performance claims were false and unsubstantiated "because of the methylene chloride problem."

"Consumers paid $50 for a product that they thought would promote good health, only to find that it might pose an additional potential hazard," Judge Timony wrote.

After learning of the filter problem, "Norelco allowed unsuspecting consumers to buy and use the remaining 214,000 contaminated filters that remained in its warehouse and the thousands still available on the retail shelf and in Norelco's own ... stores," according to the decision. In 1986, after being contacted by the FTC and other governmental agencies, Norelco decided to notify consumers about the problem and offer a replacement filter. "Although ... [the company] sold more than 248,000 Clean Water Machines, it sent notices only to its trade customers and to 19,188 consumers."

Under the judge's order, Norelco cannot make the challenged false claims for the Clean Water Machine or any other product that treats water, and cannot misrepresent any test or study of its products. In addition, it cannot misrepresent, and must have substantiation for, any performance claims it makes for any electrical-powered consumer appliance. Such appliances include hair dryers, makeup mirrors, coffee makers, and razors.

North American Philips is one of the world's largest electronics companies, and produces and sells consumer and commercial lighting and electrical products. Its Norelco Consumer Products Division is a leader in the electric housewares industry. It is based in New York City.

The judge's order is subject to review by the full Commission on its own motion or at the request of either party. If the order is not appealed and is not independently reviewed by the Commission within 30 days, it becomes the final Commission order.

Copies of the initial decision are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W. Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181

(Docket No.9209)

(Norelco)

North America Philips Corp.

D. 9205

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: August 4, 1987

FTC CHARGES THAT MAKER OF NORELCO WATER CLEANER FAILED TO DISCLOSE THE PRODUCT ADDS A POTENTIALLY HAZARDOUS CHEMICAL INTO THE WATER

The Federal Trade Commission today charged in an administrative complaint that North American Philips Corp. made false and unsubstantiated advertising claims for its Norelco brand Clean Water Machine. According to the complaint, the company claimed the machines would make tap water clean or cleaner, when the machines' filters actually added a chemical that is potentially hazardous to consumers' health.

North American Philips is one of the world's largest electronics companies. The company produces and sells consumer and commercial lighting and electrical products. The Norelco Consumer Products Division is a leader in the electric housewares industry, and sells such products as shavers and coffee makers.

The Clean Water Machine was designed to remove contaminants from tap water by forcing the water through an activated charcoal filter.

The company made claims in its ads such as, "The Norelco Clean Water Machine helps remove chlorine, sediment, sulfur, detergent, odors, organic chemicals, and other pollutants you may not even be aware of that are in your tap water," and "Helps make tap water 'bottled water' clean."

Through these and other ads and promotional materials, the complaint charged, North American Philips claimed that the Clean Water Machine would effectively help remove organic chemicals from tap water and make it clean or cleaner. In fact, according to the complaint, these claims were false and misleading because, while the machine may help remove some organic chemicals, pollutants, and impurities from the water to the extent that they exist, it added methylene chloride.

The FTC complaint also charged that North American Philips failed to disclose to consumers that original filters sold with the machine, and many of the replacement filters, were made with a glue that adds an organic chemical, methylene chloride, to the tap water. According to the complaint, the chemical is potentially hazardous to consumers' health. The complaint charged that, in light of the advertising and packaging claims made, the company's failure to disclose that the filters add a chemical to the water is a deceptive practice that violates the FTC Act.

Further, the complaint charged, the ads falsely claimed that independent laboratory tests proved that the machine made tap water clean or cleaner under typical water conditions.

The Commission issues a complaint when it has "reason to believe" that the law has been or is being violated, and where it appears to the Commission that a proceeding is in the public interest. Such action marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

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If the Commission's charges are upheld, North American Philips could be prohibited from falsely claiming that the Clean Water Machine, or other water treatment device, helps remove organic chemicals or other pollutants from tap water. The company could also be required to have a reasonable basis for all performance-related claims for any electric-powered consumer appliance sold under the "Norelco" trademark.

In addition, if the charges are upheld, the FTC may seek consumer redress. This redress would be intended to supplement North American Philips' voluntary filter replacement program, in effect since March 1986. According to the FTC staff, the company's recall letter stated that any consumer or retailer who has a filter that adds methylene chloride can return it to Norelco in exchange for one that does not add the chemical. The filters containing the chemical either do not have a date code, or have a date code of 472 or lower molded on the underside of the filter dial.

Norelco distributed the machines beginning in 1982. While Norelco no longer distributes the machines or problem filters, the FTC staff believes some are still available in retail stores.

North American Philips is based is New York.

Copies of the complaint and proposed order are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Dee Ellison, Office of Public Affairs, 202-326-2177
STAFF CONTACT:	Joel Winston, Bureau of Consumer Protection, 202-326-3153
	Michael Dershowitz, Bureau of Consumer Protection, 202-326-3158

FTC Docket No. 9209

[norelco]

Removatron International Corp. Final decision D.9200
Issued 11/4/88

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: November 9, 1988

FTC FINDS MAKER OF ELECTRONIC HAIR-REMOVAL DEVICE MADE FALSE AND UNSUBSTANTIATED CLAIMS; REQUIRES COMPANY TO HAVE SCIENTIFIC EVIDENCE FOR FUTURE CLAIMS

The Federal Trade Commission has ruled that Removatron International Corp., the largest maker of high-frequency, tweezer-type hair-removal devices, made false and deceptive claims that its devices permanently remove hair and lacked a reasonable basis for making such permanency claims. The Commission issued an order prohibiting the company from making unsubstantiated claims about its product and requiring it to possess clinical testing as substantiation for future permanency claims.

The Commission decision, written by Commissioner Terry Calvani, upholds a July 1987 ruling by Administrative Law Judge Montgomery K. Hyun. Judge Hyun's decision in turn upheld a 1985 FTC administrative complaint issued because the Commission had "reason to believe" that Removatron and its president, Frederick E. Goodman, were violating the law. The FTC complaint alleged that respondents claimed, without a reasonable basis, that the Removatron device permanently removed hair. The Commission also charged respondents with falsely claiming that they possessed a reasonable basis for their permanency claims.

Removatron International Corp. sells an electronic device called "Removatron," that removes hair with tweezers that transmit radio waves to individual hair roots through radio waves. Respondents claimed that the Removatron hair removal method eventually destroys the hair tissue and prevents regrowth of the hair. The company sells its devices to beauty salons, skin care establishments, and other businesses for about $4,000. They, in turn, sell hair-removal treatments to customers for $30-35 per hour. In 1986, Removatron had an estimated 80 percent share of the market for its product.

The Commission upheld Judge Hyun's finding that respondents' advertising and promotional materials made express and implied claims that the Removatron device permanently removes hair and that their claims were supported by a reasonable basis consisting of scientific proof.

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In addition, the Commission concluded, because the company represented that its claims were based on scientific evidence, Removatron was required to possess evidence that would satisfy the scientific community that the particular claims were true. In this case, the Commission determined, the evidence had to consist of "controlled clinical testing." In concluding that respondents possessed "no clinical evidence whatsoever," the Commission affirmed the Judge's finding that respondents did not have competent and reliable scientific tests in support of their claims.

Based on these conclusions, the Commission upheld Judge Hyun's finding that Removatron's failure to possess adequate substantiation rendered its advertising false and deceptive under the FTC Act. The Commission further stated, "we affirm Judge Hyun's finding's concerning the seriousness and deliberateness of Respondent's violations."

The Commission order is identical to Judge Hyun's, except for modifying the substantiation provision and deleting a provision requiring notification of future purchasers. The order prohibits Removatron and Goodman from making claims that any hair removal device, product, or treatment will achieve permanent, long-term, or effective hair removal, unless they rely on "competent and reliable scientific" evidence to substantiate such claims. The order defines "competent and reliable scientific" evidence as "adequate and well-controlled, double-blind clinical testing." The Judge's order had specified that the company was required to substantiate its claims with at least two well-controlled clinical tests.

The order also prohibits Respondents from misrepresenting the existence, contents, or conclusions of any test or study.

In addition, the order requires that, for a period of five years, the company and Goodman include the following disclosure with any claim that the Removatron or any similar device can remove hair: "IMPORTANT: There is no reliable evidence that (name of device) provides anything more than temporary hair removal."

The order further requires respondents to send a copy of the order to each purchaser of the Removatron device since January 1986. However, the Commission deleted the Judge's requirement that the company provide future purchasers with a copy the order. The Commission stated that it believes the order is sufficiently broad that it will achieve the Judge's goal of preventing future purchasers of the device from making prohibited claims to treatment purchasers.

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Finally, the Commission upheld the Judge's decision that respondents' claim that the Removatron device was "FCC-approved" falsely and deceptively implied that the Federal Communications Commission had approved the company's hair-removal method. The order prohibits the company and Goodman from claiming that the Removatron or any similar device is FCC-approved unless they disclose that the FCC has only approved the use of a certain radio frequency by the device and has not approved its safety or effectiveness.

Commissioners Mary L. Azcuenaga and Andrew J. Strenio, Jr., issued separate statements concurring in part and dissenting in part from the Commission opinion and order. Commissioner Azcuenaga said she agreed that Removatron made unsubstantiated claims that its product removed hair permanently, but would have required two clinical tests to substantiate claims. She said in her statement, "I do not agree that one controlled clinical test would provide sufficient substantiation for Removatron's permanency representations. I also dissent from the Commission's failure to require respondents to provide a copy of the order to future purchasers of the Removatron device. Finally, unlike the majority, I would not order respondents to continue to disclose that there is no reliable evidence that their device removes hair permanently even if they are able to produce such evidence at some future time."

Commissioner Strenio said in his separate statement that he agreed with the finding that respondents made unsubstantiated claims that Removatron removes hair permanently. He also said he agreed with the majority that in ads where respondents claim to have scientific evidence, they must have proof that would satisfy the scientific community. However, Commissioner Strenio agreed with Commissioner Azcuenaga that for claims not asserting possession of scientific proof, "respondents should be required to rely upon at least two well-controlled clinical tests" before making claims that the Removatron epilator removes hair permanently.

Both Removatron and Goodman are located in Boston.

Copies of the Commission decision and order are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W. Washington, D.C. 20580; 202-326-2222, TTY 2020-326-2502.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs,
202-326-2177

[REMOVDEC]

Removatron International Corp. D.9200 II

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: July 23, 1987

FTC JUDGE UPHOLDS COMMISSION CHARGES THAT MAKER OF ELECTRONIC HAIR-REMOVAL DEVICE MADE FALSE AND UNSUBSTANTIATED CLAIMS

Order Prohibits Company From Such Claims in the Future

A Federal Trade Commission administrative law judge has ruled that Removatron, the largest maker of high-frequency, tweezer-type hair-removal devices, deliberately made false and unsubstantiated advertising claims that the product could permanently remove hair, and he issued an order prohibiting such claims in the future.

Administrative Law Judge Montgomery K. Hyun upheld a 1985 FTC administrative complaint. According to Judge Hyun, the company's false and unsubstantiated advertising claims "are serious because they not only caused substantial financial injury to Removatron purchaser-operators and Removatron treatment customers, but also caused profound emotional injury to Removatron patrons by causing severe emotional distress."

Removatron International Corp. sells an electronic device that allegedly removes hair permanently by heating hair roots through radio waves transmitted from the device to individual hairs by electronic tweezers. The company sells its devices to beauty-salon owners and others for about $4,000. They, in turn, sell hair-removal treatments to customers for $10 to $35 per treatment. Some customers have spent as much as $3,000 to $6,000 on Removatron treatments over several years.

According to Judge Hyun, the company's advertisements are deceptive because they contained important claims about the effectiveness of its devices that are likely to mislead purchasers and customers acting reasonably. He stated that the company's violations are "serious and deliberate and their unlawful practices are readily transferable to hair removal products or devices" other than Removatron. He concluded that the company's violations are also serious because of their wide scope and long duration. "The company has been making unsubstantiated efficacy claims since they began advertising the Removatron device in 1976."

Judge Hyun upheld FTC charges that the company lacked substantiation for its claims that Removatron treatments remove hair permanently. According to Judge Hyun, failure to have a reasonable basis for these claims is a deceptive practice that violates the FTC Act. His order requires the company to have at least two well-controlled clinical tests that substantiate any future efficacy claims for any product concerning permanent or long-term hair removal.

In addition, according to Judge Hyun, the company claimed that clinical tests proved Removatron was superior. However, he concluded, "these specific and express claims are not supported by adequate substantiation." In fact, according to the judge, the company's own publication states that treated hair "usually returns in the form of

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fine hairs" which, in time, grow back into "the original type of hair." He stated, "respondents have not produced a single clinical test to establish that a series of Removatron treatments results in permanent hair removal in humans."

The Judge also upheld FTC charges that Removatron's claims that the device was "FCC approved" falsely and deceptively implied the Federal Communications Commission had approved the company's hair-removal method. He concluded that these claims are false and that they violate the FTC Act. In fact, he said, the company admits the FCC's approval merely signified that operation of the Removatron device would not interfere with radio broadcasts.

The order prohibits the company, for five years, from claiming that Removatron or any other high frequency tweezer-type device is able to remove hair unless it makes the following disclosure: "IMPORTANT: There is no reliable evidence that [name of device] provides anything more than temporary hair removal."

Under the order, the company cannot misrepresent the existence, contents, validity, results, conclusions or interpretations of any test or study. According to Judge Hyun, this provision is needed because of the company's past misrepresentations and misuse of test results and similar reports.

Judge Hyun's order also prohibits the company from claiming that the Removatron device, or any treatment using such a device, is approved by the FCC, unless it discloses that the FCC has only approved the use of a certain radio frequency and not the safety or effectiveness of the product.

The order requires the company to provide past purchasers of Removatron with a copy of the order and a notice that they must discontinue use of any of the company's advertising and promotional materials containing the prohibited claims. The company must also provide future purchasers of hair-removal devices with a copy of the order.

Judge Hyun also upheld FTC charges against Removatron's chief officer, Frederick E. Goodman, and the order applies to him as well. Goodman and the company are based in Boston.

According to Judge Hyun, the company's gross sales for Removatron and related accessories from April 1980 to September 1983 was more than $2.3 million, with the company having an estimated market share of about 80 percent. The company advertised its product mainly in trade magazines aimed at the owners and operators of beauty salons.

The full Commission may review the judge's order on its own motion or at the request of either party. If the order is not appealed or the Commission does not review it independently within 30 days, it becomes the final Commission order.

Copies of the initial decision are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Dee Ellison, Office of Public Affairs, 202-326-2177

FTC Docket No. 9200

[removatron]

Removatron International Corp. - Complaint

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: October 3, 1985

FTC CHARGES MAKER OF ELECTRONIC HAIR-REMOVAL DEVICE WITH DECEPTIVELY CLAIMING DEVICE PERMANENTLY REMOVES HAIR

The Federal Trade Commission has charged the maker of the Removatron brand hair-removal device with deceptively advertising that the product can permanently remove hair and falsely claiming the device has been approved by the Federal Communications Commission. The FTC made its allegations in an administrative complaint announced today.

Removatron International Corp. sells its electronic device to beauty-salon owners and others, who, in turn, sell allegedly permanent hair-removal treatments to consumers for approximately $35 a session. The FTC staff estimates that individuals can spend an average of $360 a year before deciding to stop Removatron treatments. Some consumers have spent as much as $6,000 for a series of unsuccessful treatments.

The FTC charged the company lacked substantiation for its claims that Removatron treatments remove hair permanently and are an effective alternative to electrolysis. Electrolysis involves inserting a needle-like probe into each hair root and heating each root until it is destroyed. In contrast, the Removatron device allegedly removes hair permanently by heating hair roots through radio waves transmitted from the device to individual hairs by electronic tweezers. Although the device may remove hair temporarily, the FTC alleged that the company did not have a reasonable basis for its claims of permanent hair removal.

The FTC also alleged the company's claims that the device was "FCC approved" falsely and deceptively implied the FCC had approved Removatron's hair-removal method. In fact, the FCC's approval signified only that operation of the device, which uses high-frequency radio waves, would not interfere with radio broadcasts.

The FTC's Boston Regional Office staff, which handled the investigation, estimates that there are at least nine firms in the country, including Removatron, that make electronic hair-removal devices and that consumers spend nearly $37.5 million a year on these treatments.

If the Commission finds the company in violation of the law, it said it could, among other things:

- — prohibit the company from claiming that the Removatron device or treatments permanently remove hair or have any long-lasting effects, unless it has adequate substantiation;
- — require the company to include affirmative disclosures in all of its ads and promotional materials, detailing the device's limitations; and
- — prohibit the company from claiming the device has been approved by any government organization unless it also discloses the exact nature of that approval.

In addition to charging the company, the FTC also charged Removatron's chief officer, Frederick E. Goodman. Goodman and the firm are based in Boston.

Issuing an administrative complaint starts a proceeding in which the Commission's allegations will be ruled upon by an administrative law judge after a formal hearing.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638.

News media copies are available from the Office of Public Affairs, Room 496, same address; 202-523-1585.

# # #

MEDIA CONTACT: Mario A. Baldassari, Office of Public Affairs,
202-523-1585

STAFF CONTACT: Phoebe D. Morse, Boston Regional Office,
617-223-6621

(File No. 842 3219)

(removatron)

Pantron I Corp. Complaint filed 11/14/88 C.D. Cal.

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: November 18, 1988

FTC CHARGES THAT BALDNESS CURE CLAIMS FOR "HELSINKI FORMULA" ARE FALSE; SEEKS INJUNCTION AND CONSUMER REFUNDS

The Federal Trade Commission has charged that advertising claims that "Helsinki Formula" products will cure or prevent baldness are false and deceptive. The Commission filed its complaint in federal court against Pantron I, Corporation, two related companies, and their principal officer.

The complaint alleges that "Helsinki Formula" was advertised by various means, including 30-minute television commercials produced especially for Pantron, called the "Discover" program and "Robert Vaughn Discovers." The company made such claims as "All [test] results were positive and concluded that the Helsinki Formula was, indeed, a valid treatment for hair loss," and "Loss of hair reduced within 2 to 3 weeks from start of treatment."

The complaint charges that the defendants falsely claimed that the product:

-- curtails hair loss, thus relieving or preventing baldness, including male pattern baldness;

-- promotes the growth of new hair where hair has already been lost, thus curing or reversing the advance of baldness, on persons including those who have male pattern baldness or have become totally bald; and

-- is an effective remedy for baldness, including male pattern baldness, in a large majority of cases.

In addition, according to the complaint, the defendants falsely represented that they had competent and reliable tests or studies to substantiate their claims.

As a result of these false claims, consumers have suffered "substantial monetary injury" and the defendants "have received and continue to receive substantial unjust enrichment," the complaint alleges. The Commission asked the U.S. District Court for the Central District of California to issue preliminary and permanent injunctions and order the defendants to pay refunds to consumers.

The three companies named in the complaint are: Pantron I, Corporation; Pantron I, Corp.; and Pantron III, Corp. They are all based in Los Angeles. The complaint also names Hal Z. Lederman, alleged to control the companies, who lives in Toluca Lake, Calif.

The case is being handled by the FTC's Seattle Regional Office.

Copies of the complaint will be available soon from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W. Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181

STAFF CONTACT: George Zweibel, Seattle Regional Office, 206-442-4656

(FTC File No. 872 3191)

(Civil Action No. 88-6696RG(Ex))

(Helsnki)

California Pacific Research Inc. Complaint filed 11/14/88 D. Nev.

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: November 18, 1988

FTC CHALLENGES CLAIMS MADE FOR "NEW GENERATION" BALDNESS PRODUCTS
Seeks Injunction and Consumer Refunds

The Federal Trade Commission has charged California Pacific Research, Inc. (CPR) and its owner, Robert Murphy, with falsely advertising "New Generation" baldness preventative and remedy. The complaint was filed on November 14, 1988 in the U.S. District Court for the District of Nevada.

The complaint alleges that CPR markets a combination of shampoos and cleanser/conditioners, known collectively as "New Generation," claiming that they reduces excessive hair loss and promotes new hair growth for individuals with male pattern baldness. The product contains polysorbate-60, among other ingredients, in a formula allegedly developed and tested at the University of Helsinki, Finland. It has been advertised by various means, including 30-minute television commercials. The complaint alleges that the company made such claims as: "[H]undreds of thousands of men and women have found that this exceptional product stops excessive hair fallout and has promoted new hair growth"; and "[o]ur testing program showed that about 90 percent of the users will experience a significant reduction in abnormal hair loss within 3 to 4 weeks of proper use. Of the approximately 80 percent that will start regrowing their hair, about 75 percent should notice new hair in 8 to 12 weeks."

The complaint alleges that the advertisements falsely represent:

* that New Generation reduces excessive hair loss in virtually everyone who has male pattern baldness; and

* that New Generation will promote new hair growth in a substantial number of individuals who have male pattern baldness.

The complaint further alleges that as a result of these false claims, consumers have suffered "substantial monetary injury" while the defendants "have enjoyed, and continue to enjoy, substantial monetary gains." It asks the court to issue preliminary and permanent injunctions and to order the defendants to pay refunds to consumers.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave., Washington, D.C. 20580; 202-326-2222; TTY 202-442-4656.

(FTC File No. 882-3167)

MEDIA CONTACT: Anna Holmquist Davis, Office of Public Affairs
202-326-2183

STAFF CONTACT: Michael Dershowitz, Office of Consumer Protection
202-326-3158

(Civil Action No. N-88-602-BRT)

(New Generation)

Spinal Health Services Inc. C-3122 Final Consent 10/13/83

FTC NEWS NOTES

Laser facelifts

CHIROPRACTORS AGREE NOT TO MISREPRESENT "LASER FACELIFTS," UNDER FTC CONSENT

Two Florida chiropractors have agreed not to claim their $750-$1500 "laser facelifts" are effective unless they have scientific proof, under a Federal Trade Commission consent agreement announced.

According to a complaint issued with the settlement, Fred J. Gehl and Samuel Lux claimed their "Facelift Without Surgery" is an "attractive alternative" to surgery. "Look years younger --this treatment will flatten lines, pull up sagging bags and skin," their ads said.

However, the complaint charges, the chiropractors had no reasonable basis for claiming the laser treatments "reduce, smooth out or remove facial lines, depressions and wrinkles, and result in a non-surgical facelift." In addition, claims that the treatments "provide long-lasting improvement in recipients' facial appearance, or improvement lasting about as long as that of a surgical facelift" were unsubstantiated, according to the complaint.

Gehl and Lux and their treatment centers, Spinal Health Services Inc. and Laser Toning Center Inc., offer "laser facelift" treatment programs of 12 to 20 or more weekly or biweekly sessions. The "facelifts" consist of applications of a beam of light from a very low-power helium-neon laser device to various facial areas, such as lines and acupuncture points. Unlike other, more powerful lasers used for surgery, this "cold" laser is comparable in power to the laser price scanners used at supermarket checkout counters.

Gehl and Lux did not produce reliable evidence that the procedure actually works when asked to do so by the FTC staff. Under the agreement, which also names the treatment centers, the two chiropractors may not represent their "facelifts" are effective or are equivalent to surgery, unless they have adequate substantiation that provides a reasonable basis for the representations. The substantiation must consist of a competent and reliable scientific test or other competent and reliable evidence, under the order. If they make claims of effectiveness for the laser "facelift" in the future, they must keep all substantiating documents constituting the reasonable basis for three years after the representations are last made.

Gehl, who does business in Miami, is an officer of the two treatment centers, and also does business at Laser Toning Center in Bay Harbor Islands, Fla. Lux, an officer of Spinal Health Services, is based in Pembroke Pines, Fla.

The consent agreement is scheduled to appear in the Federal Register Aug. 1. It will be subject to public comment until Sept. 31.

(7.27.83) (File No. 822 3165)

# # #

Comments on matters placed on the public record and mentioned in News Notes should be addressed to the Office of the Secretary, FTC, 6th and Pennsylvania Avenue, N. W., Washington, D.C. 20580.

Reproductive Genetic [illegible] Center Ltd. [illegible]
Dr. Cecil B. Jacobson

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR IMMEDIATE RELEASE: January 18, 1989

FTC CHARGES D.C.-AREA "INFERTILITY SPECIALIST" WITH MISREPRESENTATIONS, SEEKS INJUNCTION

The Federal Trade Commission has charged Dr. Cecil B. Jacobson, who ran the Reproductive Genetic Center Ltd. in Vienna, Va., with misrepresenting that women who underwent his medical treatments were virtually certain to have successful pregnancies. The FTC has also asked a federal court to issue a preliminary injunction prohibiting false claims by Jacobson.

Jacobson told women who have had difficulty becoming pregnant that they are "extremely likely or certain" to become pregnant and have a baby as a result of his treatment. In fact, the majority of his patients do not have babies as the result of his treatments, the FTC charged.

In addition, he also told women that they were pregnant as a result of his treatments, when in fact they were not pregnant, the complaint charged.

The complaint further charges that Jacobson, after telling women they were pregnant, later told them that their pregnancies had terminated. This was false because the women were not pregnant in the first place, according to the complaint.

The Commission asked the U.S. District Court for the Eastern District of Virginia, Alexandria Division, to issue preliminary and permanent injunctions blocking future misrepresentations by Jacobson.

During their first visit, Jacobson generally promised women who have had difficulty conceiving children that his treatment would produce a child, but he did not give them a physical examination. He gave the women repeated injections of a hormone, which, according to the FTC staff, is known to cause positive readings on urinary pregnancy tests when there is, in fact, no pregnancy. After several weeks, Jacobson told the women they were pregnant. Subsequently, he would perform ultrasound tests or sonograms, which he reported showed evidence of pregnancy.

Associated Mills, Inc. Complaint (water treatment)

FTC news

Federal Trade Commission Washington, D.C. 20580

FOR IMMEDIATE RELEASE: January 13, 1989

FTC CHARGES ASSOCIATED MILLS HAD NO SUBSTANTIATION FOR WATER CLEANER CLAIMS; COMPANY AGREES TO SUBSTANTIATE FUTURE CLAIMS

The Federal Trade Commission charged that Associated Mills Inc. had no basis for claiming that its Pollenex Bottled Water Maker Reverse Osmosis System could remove certain hazardous organic chemicals from tap water for a year. Under a consent agreement issued today for public comment, the company agreed to have substantiation for future similar claims.

According to the Commission's complaint, Associated Mills made such ad claims as "Removes up to 99% of organic chemicals and other contaminants from tap water" and "The membrane cartridge supplied will last for 1 year or more." The ads also claimed that the Bottled Water Maker would remove nearly all or most of the trihalomethanes, a class of hazardous organic chemicals including chloroform, contained in normal tap water for a year. However, the complaint charged, Associated Mills had no basis for making that claim.

Under the consent agreement, Associated Mills agreed to have a reasonable basis for any claims of performance characteristics of the Bottled Water Maker or any other water treatment appliance or product. It must also have a reasonable basis for claims of the expected life over which any environmental treatment product can treat or remove any contaminant or reduce any health-related risks.

Associated Mills is based in Chicago, The FTC's San Francisco Regional Office handled the investigation.

The consent agreement is scheduled to appear in the Federal Register January 18. It will be subject to public comment for 60 days, until March 20, after which the Commission will decide whether to make it final.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint, and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181

STAFF CONTACT: Janet Grady, San Francisco Regional Office, 415-995-5220

(FTC File No. 872 3075)

(Water)

Campbell Soup Co. Complaint issued 1/26/89

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: January 26, 1989

FTC CHARGES CAMPBELL SOUP CO. WITH FAILING TO DISCLOSE THE SODIUM CONTENT OF ITS SOUPS; ISSUES ADMINISTRATIVE COMPLAINT

The Federal Trade Commission today issued an administrative complaint charging Campbell Soup Co. with making deceptive and unsubstantiated claims in advertisements for its soups. The ads link the low fat, low cholesterol content of its soups with a reduced risk of some forms of heart disease, but fail to disclose that the soups are high in sodium and that diets high in sodium may increase the risk of heart disease, according to the complaint. In light of the representations made in the ads, the company's failure to make this disclosure is deceptive, the complaint charged.

FTC Bureau of Consumer Protection Director William MacLeod said, "Health-related information is important to consumers, and advertising is a principal source of that information. This is why the Commission demands accuracy in advertising."

Campbell claims in ads that are part of its "Soup is Good Food" advertising campaign, that most of its soups, including Chicken Noodle, are low in fat and cholesterol, according to the complaint. In addition, the complaint states, the ads also claim that the soups, as part of a diet low in fat and cholesterol, may help reduce the risk of some forms of heart disease.

According to the complaint, Campbell represents in its ads that it has substantiation for the claim that most of its soups make a positive contribution to a diet that reduces the risk of heart disease. However, the complaint charged, Campbell did not have substantiation for its claims, and the representation that it did is false, misleading, or deceptive.

The Commission issues a complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The issuance of a complaint is not a finding or ruling that the respondent has actually violated the law. Such action marks the beginning of a proceeding in which the allegations will be ruled upon after a formal hearing.

If the Commission finds that Campbell violated the law, it may order the company to notify consumers of the sodium content of its soups in certain advertisements. Specifically, for soup that contains more than 500 milligrams of sodium per eight ounce serving, the Commission may require the company to disclose the soups' sodium content in any ad that directly or by implication mentions heart disease in connection with the soup.

The order may also prohibit Campbell from advertising that its products can contribute to a diet that reduces the risk of heart disease, unless it has substantiation for its claims.

Campbell is a conglomerate that sells many well-known food product lines, including soups. According to trade sources, Campbell controls about two-thirds of the $2.2 billion retail soup market in the United States.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W. Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Office of Public Affairs, 202-326-2180

STAFF CONTACT: C. Lee Peeler, Bureau of Consumer Protection, 202-326-3090

FTC File No. 882 3032

[CAMPBELL]

Kraft Inc.

Complaint issued 6/1987

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: April 6, 1989

ALJ UPHOLDS FTC CHARGES THAT KRAFT MISREPRESENTED CALCIUM CONTENT OF INDIVIDUAL CHEESE SLICES; ORDERS END TO MISREPRESENTATIONS

Kraft Inc. falsely advertised that its Kraft Singles cheese slices contained as much calcium as five ounces of milk and contain more calcium than do most imitation slices, a Federal Trade Commission judge has ruled. The Administrative Law Judge has ordered the company not to misrepresent the nutrient content of its individually wrapped slices of cheese in the future.

The FTC issued its complaint against Kraft in 1987, charging false, misleading and unsubstantiated advertising.

One of the challenged ads said "Imitation slices use hardly any milk. But Kraft has five ounces per slice. So her little bones get calcium they need to grow." ALJ Lewis F. Parker found that "The ads' reference to the precise amount of milk in a Kraft Single, and their reference to milk and calcium can be interpreted as implying that a slice of Kraft Singles contains the same amount of calcium as five ounces of milk, and that--because there is no mention that calcium is lost in the processing of cheese -- the ads convey the milk equivalency claim."

He also ruled that that language in the ads "can be interpreted, since they refer to calcium and milk, and emphasize the amount of milk in a slice of Kraft Singles, as implying that imitation slices which, they state, use hardly any milk, contain less calcium than Kraft Singles.

The milk equivalency claim was false, he said, because a 3/4 ounce slice of Kraft Singles has approximately 70 percent of the calcium of five ounces of whole milk, and less than 68.2 percent of the calcium of five ounces of low-fat or skim milk. The smaller, 2/3 ounce slice therefore has even less calcium. "Thus, the claim that a slice of Kraft Singles contains the same amount of calcium as five ounces of milk is false." In addition, "Kraft knew when it disseminated the challenged ads that its Kraft Singles slices do not contain as much calcium as five ounces of milk, and it introduced no substantiation to support the milk equivalence claim."

Judge Parker also ruled that the claim that Kraft Singles contain more calcium than do most imitation cheese slices was false because virtually all non-diary slices contain the same amount of calcium Kraft Singles do. Kraft Singles' labels claim that it contains 15 percent of the Recommended Daily Allowance (RDA) of calcium per ounce, but the judge found, so did the imitation and non-diary slices sold by Kraft's competitors. He said, "the companies that manufacture the vast majority of the imitation slices sold in this country do not sell slices that contain less than 15 percent of the United States RDA of calcium per ounce and some contain more than this amount. Thus, the claim that Kraft Singles contain more calcium than most imitation slices is false." And again, "Kraft possessed no substantiation for the imitation superiority claim at the time the ads were first disseminated and offered none at the trial."

However, the judge found, Kraft "did not intend to make" the misrepresentations. Whether the company should have known that the false claims "could be inferred from the language of the challenged ads is debateable." He ruled, "the advertisements ... were developed by Kraft in response to the success of non-dairy imitation and substitute cheese slices, and were not intended to convey express deceptive claims about Kraft Singles to consumers."

The judge therefore limited his order against Kraft "to false and misleading claims about the amount or comparative amount of calcium or any other nutrient in individually wrapped slices of pasteurized process, imitation or substitute cheese products."

The judge's order is subject to review by the full Commission on its own motion or at the request of either party. If the order is not appealed and is not independently reviewed by the Commission within 30 days, it becomes the final Commission order.

Copies of the initial decision and order are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W. Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181

(Docket No. 9208)

(KraftID)

Kraft Inc.

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: November 30, 1988

FTC CLOSES INVESTIGATION OF PHILIP MORRIS COMPANY'S PROPOSED ACQUISITION OF KRAFT INC.

The Federal Trade Commission today announced that it has closed its investigation of Philip Morris Company's proposed acquisition of Kraft Inc. The Commission was reviewing the transaction for potential federal antitrust violations.

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MEDIA CONTACT: Anna Holmquist Davis, Office of Public Affairs
202-326-2183

(File No. 891 0011)

(Kraft)

An-Mar International Ltd. [illegible] and Marylou [illegible].

FTC news

5/9/89

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: May 9, 1989

FTC CHARGES SUNTANNING DEVICE SELLER FALSELY CLAIMED ITS PRODUCTS ARE BENEFICIAL, COMPANY AGREES TO SETTLE CHARGES UNDER AGREEMENT

The Federal Trade Commission charged that the makers of Solar Gold suntanning devices falsely advertised that the products provided health benefits and that consumers did not risk harmful side effects, such as skin cancer. A consent agreement issued today for public comment prohibits An-Mar International Ltd. Inc. from misrepresenting the safety of its products.

An-Mar sells tanning beds, facial units, overhead lamp systems and other products through widely-distributed mail order catalogues.

According to a complaint accompanying the agreement, An-Mar made such claims as, "In addition to a beautiful appearance, tanning contributes to good health by providing a positive and stabilizing effect on metabolism, respiration and blood formation. It has a beneficial effect on our power of resistance, makes us feel better and gives us stamina." The complaint charges that the tanning devices provide no health benefits, and in fact, pose a risk of the harmful side effects associated with exposure to the sun's radiation.

In addition, in ads and promotional material, models are frequently shown using the tanning devices without wearing protective eyewear. This is misleading, according to the complaint, because the tanning devices cannot be used safely without protective eyewear.

The consent agreement prohibits the company from misrepresenting that its devices provide health benefits and that they do not pose a risk of any harmful side effect.

In addition, the company must clearly and conspicuously disclose in promotional materials that protective eye wear is needed to prevent injury. If the material depicts models wearing ordinary sunglasses, it must also disclose that sunglasses do not offer adequate protection.

For one year, the company must include this notice in all promotional material: "NOTICE. Read the mandatory FDA warning label found on every tanning machine for important information on potential eye injury, skin cancer, skin aging and photosensitive reactions."

The complaint and consent agreement also name the company's officers, Andrew and Marzenna Bobel. An-Mar is based in Wood Dale, Ill. The investigation was handled by the FTC's Cleveland Regional Office.

The consent agreement is scheduled to appear in the Federal Register May 9. It will be subject to public comment for 60 days, until July 10, after which the Commission will decide whether to make it final.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint, and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-326-2181
STAFF CONTACT:	Mark Kindt, Cleveland Regional Office, 216-522-4210

(FTC File No. 882 3163)

(AnMar)

Body by Design and Donald and Dinah Simonini
Complaint issued 3/17/89

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: May 17, 1989

FTC CHARGES BOSTON HEALTH CLUB FALSELY REPRESENTED EFFECTS OF ELECTRIC MUSCLE STIMULATION TREATMENTS; CLUB AND OWNERS AGREE TO SETTLE CHARGES

The Federal Trade Commission has charged Body By Design, a Boston health club, and its former owners with falsely claiming that its electric muscle stimulation treatments produced the same effects as exercises. Under a consent agreement announced today for public comment, the club and owners agreed not to misrepresent any fitness program in the future.

According to a complaint accompanying the agreement, Body By Design claimed that its electric muscle stimulation program would "Exercise 20 muscle groups simultaneously and achieve up to 1000 muscle contractions as in situps, pushups and leglifts," that men would "develop the 'V' shape", and that women would "tone stomachs, thighs, and buttocks." The claims implied that the program provided greater health benefits and increases in strength for normal healthy people than a regular rigorous exercise program would, the complaint charged.

However, according to the complaint, the claim by the company and individuals that they had a reasonable basis for making the claims, was false and misleading.

Under the consent agreement, Body By Design and its two former owners, Dinah H. Simonini and Donald L. Simonini, agreed not to misrepresent the efficacy or comparability of any diet, strength development or fitness program or product.

The Simoninis owned and operated Nutritone Inc., which did business under the name Body By Design, until the facility was sold in June 1988. The company is based in Newton, Mass. The FTC's Boston Regional Office handled the investigation.

The consent agreement is scheduled to appear in the Federal Register May 18. It will be subject to public comment for 60 days, until July 17, after which the Commission will decide whether to make it final.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580.

A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the agreement, the complaint, and an analysis of the agreement are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT:	Susan Ticknor, Office of Public Affairs, 202-326-2181
STAFF CONTACT:	Phoebe D. Morse, Boston Regional Office, 617-565-7240

(File No. 862 3125)

(Body)

Reproductive Genetic Center Ltd. and
Dr. Cecil B. Jacobson 5/18/89

FTC news

Federal Trade Commission ***Washington, D.C. 20580***

FOR IMMEDIATE RELEASE: May 18, 1989

FTC ANNOUNCES SETTLEMENT WITH D.C.-AREA "INFERTILITY SPECIALIST," WHO AGREES TO PAY UP TO $250,000 IN CONSUMER REDRESS

The Federal Trade Commission announced that Dr. Cecil B. Jacobson, who ran the Reproductive Genetic Center Ltd. in Vienna, Va., has agreed to settle charges that he misrepresented the likelihood that his patients would become pregnant as a result of his treatments and that women who underwent his infertility treatments had, in fact, become pregnant. Jacobson agreed to pay up to $250,000 in consumer redress and also agreed to a permanent injunction forbidding future misrepresentations relating to his infertility practice, under a consent decree approved by a federal court today.

The Commission filed its complaint against Jacobson in January, charging that he gave women repeated injections of a hormone which is known to cause positive pregnancy readings on urinary pregnancy tests when there is, in fact, no pregnancy. According to the complaint, Jacobson then told the women they were pregnant and said that sonograms or ultrasound tests confirmed this. Jacobson would eventually tell the women that the pregnancies had terminated and that the fetuses had been "resorbed" or absorbed back into the woman's body, the Commission alleged.

Under the injunction, Jacobson agreed not to falsely represent:

-- the likelihood of success of getting pregnant or having a baby as a result of his treatments;

-- the past success rate of pregnancies or live births as a result of his infertility treatment services;

-- that a woman is pregnant;

-- that any examinations or tests indicate a pregnancy;

-- that a pregnancy has terminated; and

-- that an embryo or fetus has "resorbed" or otherwise disappeared.

In addition, Jacobson agreed not to represent the likelihood

Sometime later, Jacobson usually advised the women that their pregnancies had terminated and that the fetus had been "resorbed," or absorbed back into the woman's body. He frequently advised women to start treatment again, sometimes stating that they are most fertile after termination of a pregnancy. Many women repeated the cycle of treatment, according to the FTC complaint.

The complaint charges that Jacobson's false representations "have induced consumers to undergo repeated courses of treatment, thereby causing substantial financial injury in monies paid for defendants' services. In addition, such representations may have lead consumers to forego other alternatives for having children, including other treatment and/or adoption, all to consumers' substantial detriment."

Copies of the Commission's complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs, 202-326-2181

STAFF CONTACT: Michael McCarey, Bureau of Consumer Protection, 202-326-3303

(FTC File No. 882 3203)

(Civil No. 89-0078A)

(Jacobsn)

FTC

The later consent decree, entered March 24, 1969, enjoins FTD from engaging in any conduct whereby it would:

- Fix, publish or suggest minimum or maximum prices or wire service charges, except in certain limited circumstances;
- Expel members or deny membership application without written notice setting forth the reason for membership expulsion or denial;
- Prevent a member from engaging in any lawful business other than the retail florist business;
- Prevent a member from being listed in a directory of retail florists published by someone other than FTD;
- Prevent a member from being affiliated with any other floral association;
- Prevent a member from advertising prices, services, and delivery area in any advertising medium;
- Prevent a member from being listed in the FTD directory as serving a town in addition to the one in which the member is located; or
- Restrict the location of the place of business of members or applicant for membership.

That decree settled an August 1, 1966 complaint charging FTD with violations of Sherman Act Secs. 1 and 2. The complaint alleged price fixing, territorial arrangements, and agreements which excluded from FTD membership establishments not primarily engaged in the floral business.

In a memorandum explaining its tentative consent to FTD's motion, the Justice Department Antitrust Division argues that both the 1956 and 1969 final judgments prohibit practices that are not no considered per se illegal and are actually employed by other flowers-by-wire competitors who are not subject to the judgments.

Because the judgments could be construed to bar FTD from adopting more flexible, even-handed membership classifications and fee structures already being employed by its competitors, the judgments restrain competition, according to the Division.

Changes in the industry also support termination of the judgment, the Division asserts. When the 1956 complaint was filed, only two other flower-by-wire services competed with FTD. Today, however, 17 competitors exist and there is substantial multiple membership by florists in several wire services. In 1986, 80 percent of FTD's members held dual membership with one or more of the wire services in 1986.

Interested persons may submit comments to Anthony V. Nanni, Chief, Litigation I Section, Antitrust Division, Department of Justice, 555 4th Street, N.W., Washington, D.C. 20001 (telephone: 202-724-6694. Comments must be received within 60 days.☐

Advertising

FTC COMMISSIONER DEFENDS AGENCY'S RECORD ON DECEPTIVE ADS REGULATION

Federal Trade Commissioner Terry Calvani March 21 denied accusations that his agency has failed to protect consumers against deceptive advertising practices, saying that the FTC has been vigorously enforcing the law without resorting to the "over regulation" that its critics would prefer.

While those critics—including the National Association of Attorneys General—say that the FTC went "soft" on deceptive advertising under the Reagan administration, the agency in fact has brought complaints against number of national advertisers, Calvani told a conference of the American Advertising Federation.

The FTC has reformulated the legal standards it uses in deceptive advertising cases, more narrowly defining what constitutes deception. Thus, if the number of advertising cases taken on by the FTC has dropped off since 1980, it is not because the agency is failing to do its job, but rather that throughout the 1960s and 1970s the FTC was an over-zealous regulator which sometimes too broadly interpreted deceptive advertising law, he said.

Under this new interpretation of deception, almost all of the deceptive advertising cases taken on by the FTC have involved situations in which claims were made that consumers would not be likely to have sufficient information about to be able to judge the validity of the claim—predominately commercials which make claims about the health benefits of a product, he said. A recent example of this type of deceptive practice, he continued, is the FTC's filing against the Campbell Soup Co. for its ads touting its soups as aiding in the prevention of heart disease while failing to mention that the soups are also high in sodium, which has been linked to high blood pressure and heart disease (17 DER 1/27/89, A-20).

NAAG President and New York Attorney General Robert Abrams, however, charged that the FTC has forsaken its role as regulator of advertising, leaving the states to take over the role. "The FTC has virtually removed itself from the field of protecting consumers against false advertising," he said.

Abrams added that he does believe there are signs that the FTC may resume its former consumer watchdog role, citing the Campbell Soup case, which he said represents a "welcome departure from the situation that has reigned for most of this decade." Abrams expressed hope that the Bush administration intends to pay more attention to consumer protection, adding that the president's choices for FTC chairman and for chief of the Justice Department's antitrust division will be a good indication of whether the new administration is committed to protecting consumers.

Legislative Agenda

Congress, meanwhile, will also be looking at advertising regulation this year, according to members who spoke at the conference, particularly at possible further restrictions on the advertisement of tobacco products and limits on advertising during children's television programs.

Legislation from last year placing quantitative limits on the number of commercials that can be shown during children's programs will be introduced soon and marked up by the House Energy and Commerce subcommittee on telecommunications probably the

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week of April 3, according to Rep. Thomas Tauke (R-Iowa), a member of the subcommittee. The legislation will be identical to the bill passed by Congress last year and pocket vetoed by President Reagan, he said. Tauke, who is opposed to the legislation, expressed hope that it also will be rejected by President Bush. A better approach, he suggested, would be to allow the broadcast industry to set its own guidelines on advertising during children's shows. However, Rep. Norman Lent (R-NY) ranking minority member for the committee, said that he will support the legislation, which he said addresses the "special needs" of children and is not an attempt to turn back the clock on broadcast deregulation.

A number of bills which would place further restrictions on print advertisements for tobacco products have already been introduced this year, with more expected, and the issue will be a high priority for Congress, Lent said. However, whether legislation will make it through the House and Senate is unclear, he added, noting that although hearings were held on legislation introduced in the last Congress, no mark-ups were held.

Congress may also attempt to take up reauthorization legislation for the FTC, but it is not as high a priority, Lent said. Congress has not passed reauthorizing legislation for the agency since 1982.☐

Foreign Investment

U.S. AIMING TO BALANCE LAW, OPEN POLICY UNDER EXON-FLORIO PROVISION, OFFICIAL SAYS

The Interagency Committee on Foreign Investment in the United States is attempting to implement the Exon-Florio provision of the 1988 omnibus trade law "in a way that is consistent with both the spirit of the law and the administration's open investment policy," a Treasury Department official said March 21.

Don Crafts, an economist with Treasury's Office of International Investment, said, however, that "it has been difficult and it's going to be difficult" for CFIUS to achieve that balance.

Crafts made his remarks to a seminar on foreign investment in the United States sponsored by the Washington International Trade Association.

The Exon-Florio provision—written by Sen. James Exon (D-Neb) and Rep. James Florio (D-NJ)—empowers the president or his designee to investigate certain proposed foreign acquisitions of U.S. companies and, if necessary, to block those transactions that could "threaten to impair the national security" of the United States.

Responsibility for enforcing the provision was given to CFIUS last December. The panel is chaired by Treasury and includes representatives of seven other government agencies—the Commerce, State, Defense, and Justice departments, the Office of the U.S. Trade Representative, the Council of Economic Advisers, and the Office of Management and Budget.

Crafts said CFIUS is "working assiduously" to draft regulations to implement the provision. However, there are "a lot of very nettlesome problems" that need to be addressed in drafting the regulations, he said. These include determining what constitutes notification under the provision, who may notify CFIUS, and precisely what types of transactions are covered by the provision.

As to what constitutes "national security," Crafts said "it is clear from the legislative history" of the Exon-Florio provision that the term "is meant to be broadly defined."

Regulations Circulated

The draft regulations will have to be circulated among various government agencies before public release, Crafts said, and then they will be open to public comment. He said he hoped it would be "a couple of months, and not the rest of the year" before the draft regulations will be completed.

In the absence of regulations, Crafts advised any company engaged in a transaction involving a foreign acquirer that might have national security implications to notify Treasury. In such notifications, the Treasury official said, the types of things CFIUS looks for include descriptions of the transaction, the buyer, and the target; the buyer's plans for the acquired company; the existence of classified contracts with the U.S. government; and compliance with other applicable U.S. laws.

In response to a question, Crafts said CFIUS to date has not issued non-binding advisory opinions on proposed transactions that might fall under Exon-Florio scrutiny. Although he did not rule out the possibility that CFIUS might issue such advisory opinions, he said he doubted that would happen.

Asked whether the regulations were likely to contain "safe harbors," Crafts said that certain exemptions had been discussed, but "more in terms of exempting certain industries, and less in terms of a floor" for a transaction's size or percentage of ownership involved.

Crafts confirmed that so far CFIUS has launched three investigations under Exon-Florio, one of which has been completed.

Current Investigations

In its first and only completed investigation, CFIUS recommended that a unit of West Germany's Veba AB be allowed to acquire Monsanto Co.'s Monsanto Electronic Materials Co. subsidiary, a manufacturer of silicon wafers. President Bush accepted CFIUS' recommendation and did not intervene in the transaction.

The two investigations in progress involve the agreement by Japan's Tokuyama Soda Co. Ltd. to acquire General Ceramics, Inc., which makes, among other things, ceramic beryllium components that are used in producing nuclear weapons, and two joint ventures between Switzerland's Asea Brown Boveri, Inc., and Westinghouse Electric Corp. to manufacture and sell various electric power generation, transmission, and distribution products.

Other speakers at the seminar discussed the adequacy of the U.S. government's current system of collecting data on foreign investment and the merits of legislation that would impose additional reporting requirements on foreign investors.

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0148-8155/89/$00.50

VEDDER, PRICE, KAUFMAN & KAMMHOLZ
A PARTNERSHIP INCLUDING VEDDER, PRICE, KAUFMAN & KAMMHOLZ, P.C.
222 NORTH LA SALLE STREET
CHICAGO, ILLINOIS 60601-1003
312-609-7500
FACSIMILE: 312-609-5005

VEDDER, PRICE, KAUFMAN, KAMMHOLZ & DAY
1919 PENNSYLVANIA AVE., N.W.
WASHINGTON, D.C. 20006-3471
202-828-5000

1 DAG HAMMARSKJOLD PLAZA
NEW YORK, NEW YORK 10017-2203
212-223-4880

MICHAEL E. REED
312-609-7640

December 15, 1988

VIA FEDERAL EXPRESS
Mr. Michael C. McCarey
Associate Director for Service
  Industry Practices
Bureau of Consumer Protection
Federal Trade Commission - Room 200
Pennsylvania Ave. and 6th Street, N.W.
Washington, D.C. 20580

Dear Mr. McCarey:

This firm is general counsel to the American Society of Plastic and Reconstructive Surgeons, Inc. (the "Society"). Pursuant to 16 C.F.R. § 2.2, the Society hereby petitions the Federal Trade Commission to investigate an organization known as "Medical Marketing Services, Inc." The Society believes that this organization may be involved in deceptive acts or practices and/or unfair methods of competition in violation of § 5 of the Federal Trade Commission Act.

As indicated by the enclosed physician marketing materials (Group Exhibit A), Medical Marketing Services, Inc. aggressively markets training programs in the practice of "endodermology." The Director of Marketing for the organization, Mr. Michael Walerstein, claims that he can train physicians in the "exclusive methods of endodermology," a "safe proven system" for performing non-surgical facelifts. In addition, Mr. Walerstein states that physicians can add "$100,000 and more" to their annual incomes by engaging in the practice of endodermology.

Endodermology is not a recognized medical specialty and has no meaning in the medical lexicon. Further, it is not, as Mr. Walerstein describes it, "an exclusive system." In fact, it is a standard full face phenol chemical peel, which is well known and has been widely practiced by physicians fully trained in such procedures. The Society believes that by claiming the system is "exclusive," Medical Marketing Services, Inc. may be engaging both in deceptive practices and unfair methods of competition.

According to experts from the Society, the phenol chemical peel is an extremely delicate and dangerous procedure, which should be performed only by those fully aware of, and capable of treating, the complications that may develop therefrom. These

Mr. Michael C. McCarey
December 15, 1988
Page 2

complications may include phenol toxicity, permanent scarring and full thickness skin loss, bacterial infection, and permanent alteration of the pigmentation of the treated skin. The statement that endodermology is a "safe proven system" deceptively minimizes the substantial risks of complication associated with this procedure.

We also enclose for the Commission's review a sample patient brochure developed by Medical Marketing Services, Inc. (Group Exhibit B). The Society has received information indicating that physicians trained by Medical Marketing Services, Inc. advise prospective patients that no complications result from endodermology. Specifically, the Society learned that one such physician advised a prospective patient that endodermology does not cause infection because there is no cutting or bleeding, and does not cause any allergic reaction because the process removes the skin. Again, the Society believes that these statements deceptively minimize the substantial risks associated with the procedure.

The Society will be happy to provide any assistance requested by the Commission with respect to the investigation and looks forward to the opportunity to discuss the matter with the Commission, in person or by telephone, at its early convenience.

Very truly yours,

THE AMERICAN SOCIETY OF
PLASTIC AND RECONSTRUCTIVE
SURGEONS, INC.

By: ______________________
One of Its Attorneys

Michael E. Reed, Esq.
Vedder, Price, Kaufman & Kammholz
222 North LaSalle Street
Chicago, Illinois 60601
312/609-7640

Enclosure
cc: Thomas R. Schedler, CAE

PlasticSurger
NEWS
SOCIETY OF PLASTIC AND
RUCTIVE SURGEONS, INC.

ASPRS urges FTC to investigate endodermology

As part of its goal of protecting the public from questionable practitioners, ASPRS recently filed a formal petition with the Federal Trade Commission (FTC) to investigate so-called "endodermology" franchises and the system's marketers.

In its petition, ASPRS stated its belief that those involved in promoting the franchises are engaged in deceptive practices, and therefore are in violation of Section 5 of the FTC Act.

The endodermology technique is marketed with the promise of facial rejuvenation without surgery—popularly known as the "non-surgical facelift." However, endodermology is actually a variation on the standard chemical peel technique that's widely practiced by plastic surgeons and some dermatologists.

According to its promoters, the franchise offers participating physicians exclusive rights to market and practice the technique in a given geographic area. The promoters provide complete marketing counseling and materials, including before-and-after photos, camera-ready ads, reference letters, direct mail collateral material and physician/staff training.

The promotional material also

See Endodermology pg. 9

Endodermology

(continued from page 1)

includes cash-flow projections based on a $3,500 fee for each treatment. The estimated net profit for each participant during the first year is approximately $250,000. The cost to physicians who buy into the franchise is approximately $40,000.

Nowhere in the promotional material does the term "chemical who claimed to perform "non-surgical facelifts" and other procedures with a laser. The laser used by those practitioners was a helium-neon device that produced colored light at low densities and did not burn or penetrate the skin.

In its complaint about the laser technique, ASPRS stressed that there was no report in reputable medical or surgical literature even suggesting that the therapy could successfully restore a more youthful appearance. The Society emphasized that the claims made by practitioners advertising this type of non-surgical facelift lacked both a scientific and rational basis.

As a result of ASPRS' petition, the FTC conducted a thorough investigation and, in October 1983, issued a complaint against certain chiropractors practicing in various areas of Florida. Following the complaint, a consent decree was entered into with those chiropractors and the corporations with which they were affiliated. The FTC then widely publicized the consent decree and specifically disseminated the information to chiropractic state boards.

RECEIVED
MAR 27 1989
KANSAS STATE BOARD OF
HEALING ARTS

MEDICAL
MARKETING
SERVICES
INC.

Dear Doctor:

An additional $100,000.00 to $400,000.00 can be added to your annual gross volume immediately, when you are trained in our exclusive methods of ENDODERMOLOGY.

The NON-SURGICAL FACE LIFT is now a perfected reality. Over the last twelve months doctors have been successfully trained in the process that turns back the clock of time 10 to 20 years and more in the appearances of a wide variety of satisfied patients.

The exclusive system is responding to the ever increasing demands of the 40 year old who wants to look like she did in her 20's, the seasoned professional who needs that younger look to compete, and the wrinkled senior citizen seeking a newer fresher look.

During our training, you will be taught to remove age spots, deep lines and wrinkles, some of which cannot be achieved by surgery or injections. Your patient will be left with NEW FRESH TIGHT SKIN that has the TRUE YOUTHFUL GLOW. Remember, this is new, fresh, glowing skin -- not the stretching of old, tired skin, and offers a viable alternative to the associated risks of some surgical procedures. MEDICAL MARKETING SERVICES, INC. will teach the qualified doctor in just one week, our SAFE proven system. Your staff will be taught the complete marketing, operational and back-up procedures.

Our marketing methods can eventually produce an additional gross income of $400,000.00 and more annually, year after year without appreciably increasing your current practice overhead.

If you feel you have the necessary qualifications, and desire more information about this expansion of your current practice, please complete the enclosed questionnaire and I will personally contact you promptly.

For immediate information, please call me during business hours at (305) 493-5573 or evenings and weekends at (305) 472-8218.

Sincerely,

Michael L Walerstein

Michael Walerstein
Director of Marketing

MEDICAL MARKETING SERVICES, INC.

MW:de

860 S.W. 89th Terrace/Suite 303/Plantation, Florida 33324/305/472-8218 Outside Florida 1/800/624-3130

MEDIC
MARKETIN
SERVIC
IN

Dear Doctor:

An additional $100,000.00 and more can be added to your annual gross volume immediately, when you are trained in our exclusive methods of ENDODERMOLOGY.

The NON-SURGICAL FACE LIFT is now a perfected reality. Over the last three years doctors have been successfully trained in the process that turns back the clock of time 10 to 20 years and more in the appearances of a wide variety of satisfied patients.

The exclusive system is responding to the ever increasing demands of the 40 year old who wants to look like she did in her 20's, the seasoned professional who needs that younger look to compete, and the wrinkled senior citizen seeking newer fresher look.

During our training, you will be taught to remove age spots, deep lines and wrinkles, some of which cannot be achieved by surgery or injections. Your patient will be left with NEW FRESH TIGHT SKIN THAT HAS THE TRUE YOUTHFUL GLOW. Remember, this is new, fresh, glowing skin — not the stretching of old, tired skin, and offers a viable alternative to the associated risks of some surgical procedures. MEDICAL MARKETING SERVICES, INC. will teach the qualified doctor in just one week, our SAFE proven system. Your staff will be taught the complete marketing, operational and back-up procedures.

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Sincerely,

Michael L Walerstein

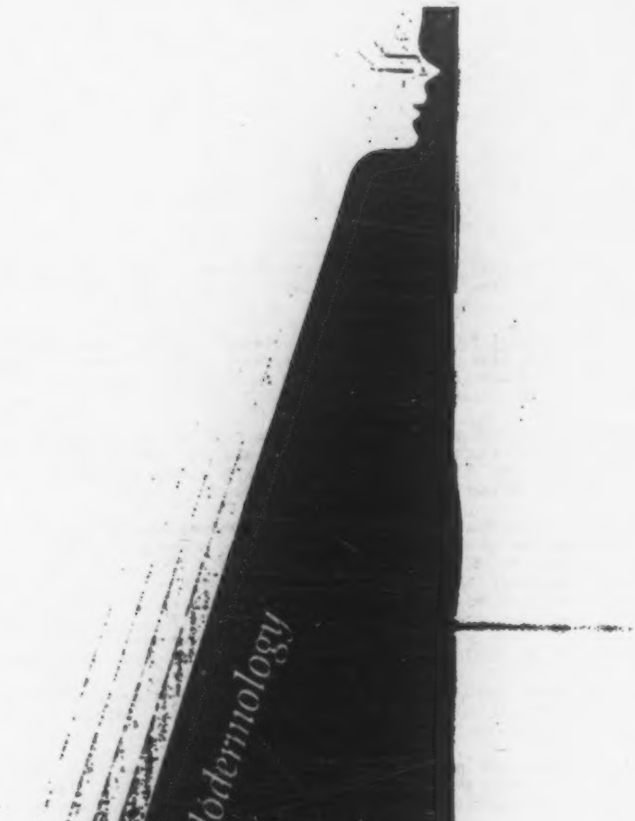
Michael Walerstein
Director of Marketing

MEDICAL MARKETING SERVICES, INC.

MW:de

GROUP EXHIBIT A

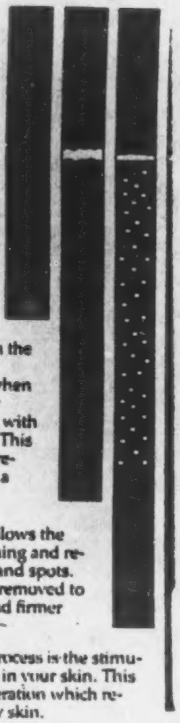
860 S.W. 89th Terrace/Suite 303/Plantation, Florida 33324/305/472-8218 Outside Florida 1/800/624-3130


Endodermology

GROUP EXHIBIT B

[illegible] Endodermology

Clearly, there are advantages in *being* older, but not *looking* older. Everyone has a point in life when their skin begins to show signs of aging–a time when they wish they could turn back the clock on nature. Thanks to the Dermology Institute of America, Inc., the days of merely wishing are over. Now, men and women are learning of a medically sound procedure designed to reduce or eliminate lines, wrinkles, brown spots. Doctors and researchers have combined extensive research to pioneer a unique process of regenerative cosmetology called endodermology.™ Previously available only to the very rich and famous, endodermology™ is now possible for anyone in good health who wants to shed 10-20 years from their appearance.



The process of endodermology™ can best be explained by understanding the composition of your skin.

There are several layers which make up the outer skin, referred to as epidermis. The effects of nature, aging and exposure to the environment (sun, wind and pollution) manifest themselves as wrinkles, spots, and roughness in the epidermis.

Endodermology™ works on the outer layers of skin. The regenerative process begins when a solution is applied to your face, neck, or hands, sealed with a surgical paper tape mask. This mask is soon removed and replaced by the application of a powdered mask.

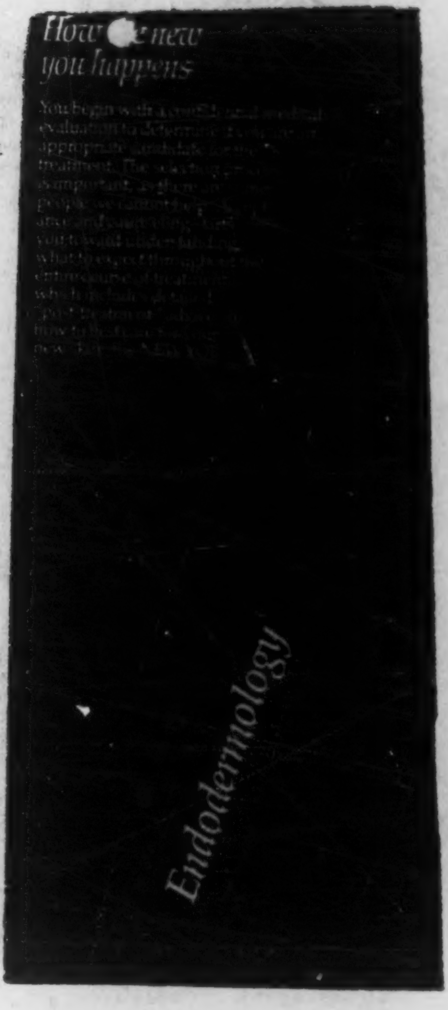
With this mask in place, it allows the solution to work at diminishing and removing the wrinkles, folds and spots. Eight days later the mask is removed to reveal, a smoother, softer and firmer texture skin.

Another advantage to the process is the stimulation of dormant cells deep in your skin. This further enhances cell regeneration which results in radiant, healthy new skin.

The most remarkable aspect of endodermology™ is the enduring effects of the process. Soft, smooth, glowing new skin will be yours for years following the treatment, and as the aging process resumes, y will always continue to look ten to fifteen years younger by taking care of your health.

AFTER
BEFORE
AFTER
BEFORE

If your personal and professional life could be enhanced by the confidence that comes with looking your best, it's time to consider endodermology.™ Imagine a treatment that leaves you with a smooth, fresh, NEW skin™ that is soft to the touch and virtually free from wrinkles, blemishes and spots in JUST 8 days. Now is the best time to call and schedule a free consultation. A professional counselor is available for your no obligation conference, held in absolute confidence.



How [illegible] new you happens

You begin with a [illegible] and medical evaluation to determine [illegible] appropriate candidate [illegible] treatment. The selection [illegible] is important, as there [illegible] people we cannot help [illegible] areas and [illegible] you toward understanding what to expect throughout the entire course of treatment which includes [illegible]

Endodermology

REC'D FEB [illegible] 1989

VEDDER, PRICE, KAUFMAN & KAMMHOLZ
A PARTNERSHIP INCLUDING VEDDER, PRICE, KAUFMAN & KAMMHOLZ, P.C.
222 NORTH LA SALLE STREET
CHICAGO, ILLINOIS 60601-1003
312-609-7500
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WASHINGTON, D.C. 20006-3471
202-828-5000

1 DAG HAMMARSKJOLD PLAZA
NEW YORK, NEW YORK 10017-2203
212-223-1880

February 22, 1989

Mr. Thomas R. Schedler, CAE
Executive Director
American Society of Plastic and
Reconstructive Surgeons, Inc.
444 East Algonquin Road
Arlington Heights, Illinois 60005

RE: Enforcement of its Code of Ethics by the American Society of Plastic and Reconstructive Surgeons, Inc.

Dear Mr. Schedler:

As you know, in October, 1980, the membership of the American Society of Plastic and Reconstructive Surgeons, Inc. (the "Society") adopted a Code of Ethics proscribing various types of conduct including conduct involving false, deceptive and misleading statements or claims by the members. A copy of the Society's Code of Ethics is attached as Exhibit A.

The Society has actively forced its Code of Ethics since it was adopted in 1980. In the following, we will briefly review the mechanism which the Society has adopted for enforcing its Code and then note the specific types of sanctions which have been imposed by the Society and the conduct giving rise to those sanctions.

An elected Ethics Committee consisting of seven members conducts investigations into alleged violations of the Society's Code of Ethics. In the event the Ethics Committee, after investigation, believes a violation may have occurred, the Committee presents the complaint and all substantiating information to the Society's hearing body, the Judicial Council which consists of five elected members. The role of the Judicial Council is to conduct hearings and reach decisions with respect to alleged violations of the Code of Ethics.

If the Judicial Council determines that a violation has occurred, it imposes one of the following sanctions: private censure; public censure; probation; suspension or expulsion. If a member disagrees with the decision of the Judicial Council, the member may appeal the decision to the Society's trustees. The trustees then conduct an appellate review to determine whether or not the decision of the Judicial Council was substantiated by the information presented. The member may and generally does appear at hearings before the Judicial Council and at appeals conducted by the trustees. The decision of the trustees on a matter is final.

The Society has conducted a total of 170 formal investigations since the Code of Ethics was adopted. It has received a much larger number of complaints but only 170 of those complaints were sufficiently serious and sufficiently well documented to warrant an investigation. In the following paragraphs, we will review those investigations which resulted in hearings before the Judicial Council and the imposition of sanctions. Some of the 170 investigations led to hearings which resulted in a finding that no violation occurred and others were terminated before the hearing stage because the Ethics Committee determined there was not a sufficient basis to proceed.

The Society has to date expelled four members for violation of its Code of Ethics. The first individual was expelled in October, 1981 for violating the Society's prohibitions against false, deceptive and misleading advertising. The second individual was expelled in October, 1982 also for violating the Society's Code prohibitions against false, deceptive and misleading advertising. The third individual was expelled in March, 1988 because his license was revoked for conviction of a felony. The fourth individual was expelled in January, 1989 for making factual misrepresentations about his qualifications while testifying under oath as an expert witness.

The Society has suspended four individuals since the adoption of its Code of Ethics. One individual was suspended in 1982 for six months followed by a three year period probation for participating in false, deceptive and misleading advertising by a medical clinic with which he was affiliated. Another individual was suspended for three years in 1982 in connection with a plea of no contest to a felony charge involving the receipt of stolen property. A third individual was suspended in 1981 for violating the Society's prohibitions against false, deceptive and misleading advertising. A fourth individual was suspended in 1985 for inappropriate billing procedures, i.e, billing for a procedure that was not performed.

Four individuals have been placed on probation for varying periods. One individual was found to have violated the Code of Ethics in connection with the submission of operative and no fault insurance reports and was placed on probation in 1983 for a period of three years. Another individual was placed on probation in 1983 for engaging in false, deceptive and misleading advertising. A third individual was placed on probation in 1984 for a period of three years for charging exorbitant fees, and a fourth individual was placed on probation in 1988 for three years for false, deceptive and misleading advertising in connection with the sale of a product.

One individual was publicly censured in 1981 for disseminating false, deceptive and misleading claims about his credentials and the clinic with which he was affiliated.

Seven individuals have been privately censured virtually all resulting from violation of the Code's provisions against false, deceptive and misleading advertising.

We trust the foregoing is responsive to your request. If you would like any further information or additional detail, please call.

Sincerely,

Michael E. Reed

gb

Encl.

EXHIBIT 'A'

Code of Ethics for the American Society of Plastic and Reconstructive Surgeons, Inc.

Preamble

As stated in its *Bylaws*, the American Society of Plastic and Reconstructive Surgeons, Inc. (ASPRS) is organized:

> To benefit humanity by advancing the art and science of plastic and reconstructive surgery; to promote the highest standard of professional skills and competence among plastic surgeons; to promote the exchange of information among plastic surgeons; to promote the highest standard of personal conduct among plastic surgeons and physicians; to provide the public with information about the scientific progress in plastic and reconstructive surgery; to promote the purpose and effectiveness of plastic surgeons as is consistent with the public interest.

Membership in ASPRS is granted by the voting Membership of ASPRS to those surgeons who are competent practitioners of the art and science of plastic surgery. Competence in plastic surgery involves attainment and maintenance of high standards of medical and ethical conduct. Medical competence is fostered by successful completion of the examinations of the American Board of Plastic Surgery. Ethical competence is fostered by the adoption and enforcement of a *Code of Ethics*, adherence to which is a prerequisite for admission to and maintenance of membership in ASPRS. Each member is expected to act in accord with the *General and Specific Principles of the Code of Ethics* of ASPRS in his contacts with patients, peers and the general public. Further, each member is individually responsible and accountable for his own actions and words, as well as the use of his name and shall be subject to disciplinary action, including expulsion, if he violates any of the *General or Specific Principles* of this Code.

Section 1.—General Principles

I. The principal objective of the medical profession is to render services to humanity with full respect for the dignity of man. Physicians should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion.

II. Physicians should strive continually to improve medical knowledge and skill, and should make available to their patients and colleagues the benefits of their professional attainments.

III. A physician should practice a method of healing founded on a scientific basis; and he* should not voluntarily associate professionally with anyone who violates this principle.

IV. The medical profession should safeguard the public and itself against physicians deficient in moral character or professional competence. Physicians should observe all laws, uphold the dignity and honor of the profession, and accept its self-imposed disciplines. They should expose, without hesitation, illegal or unethical conduct of fellow members of the profession.

V. A physician may choose whom he will serve. In an emergency, however, he should render service to the best of his ability. Having undertaken the care of a patient, he may not neglect him; and unless he has been discharged, he may discontinue his services only after giving adequate notice.

VI. A physician should provide services under terms and conditions which permit the free and complete exercise of his medical judgment and skill. Nothing contained in this provision shall be construed to limit price competition among physicians.

VII. In the practice of medicine, a physician should limit the source of his professional income to medical services actually rendered by him, or under his supervision where he is personally and identifiably responsible. He should neither pay nor receive a commission for referral patients.

VIII. A physician should seek consultation upon request, in doubtful or difficult cases or whenever it appears that the quality of medical service may be enhanced thereby.

IX. A physician may not reveal the confidence entrusted to him in the course of medical attendance, or the deficiencies he may observe in the character of patients, unless he is required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or of the community.

X. The honored ideals of the medical profession imply that the responsibilities of the physician extend not only to the individual, but also to society. Activities which have the purpose of improving both the health and well-being of the individual and the community deserve the interest and participation of the physician.

XI. To assist the public in obtaining medical services, physicians should be permitted to make known their services through advertising. Advertising, however, entails the risk that the physicians may employ practices that are false, fraudulent, deceptive, or misleading. Regulation is, therefore, necessary and in, the public interest. The *Specific Principles* governing advertising permit public dissemination of truthful information about medical services, while prohibiting false, fraudulent, deceptive or misleading communications, and restricting direct solicitation.

Section 2.—Specific Principles

I. Each member may be subject to disciplinary action, including expulsion if:

A. His right to practice is limited, suspended or terminated in any state, province, or country for violation of medical practice act or other statute or governmental regulation or he is disciplined by any medical licensing authority.

B. He exhibits medical incompetence.

C. He is convicted of a felony or of any crime relating to or arising out of the practice of medicine or involving moral turpitude.

D. He is involved in improper financial dealings such as:

1. Payment and/or acceptance of rebates or referral fees.
2. Charging exorbitant fees, particularly of non-contractual nature (e.g., emergency care). Fees are exorbitant when they are wholly disproportionate to the services rendered. The reasonableness of the fees depends upon the novelty and difficulty of the procedures involved; the skill required to provide proper care; the time and labor required; the fee charged for similar services by similarly situated peers; and whether or not the patient had agreed in advance to the fee.
3. Except in instances of emergencies or urgent and life threatening disease or injury, nothing in this Principle shall be construed to prohibit a member from requiring prepayment of professional fees for an elective surgical operation.

E. He, on behalf of himself, his partner, or associate or any physician or other healthcare provider affiliated with him or his organization, uses or participates in the use of any form of communication containing a false, fraudulent, deceptive, or misleading statement or claim includes a statement or claim which:

1. Contains a misrepresentation of fact, or omits to state any material fact necessary to make the statement, considered as a whole, not deceptive or misleading.
2. Contains images of persons or facsimiles thereof which falsely or deceptively portray a physical or medical condition, injury, disease, including obesity, or recovery or relief therefrom.
3. Contains a testimonial pertaining to the quality and efficacy of medical care if the experience of the endorser does not represent the typical experience of other patients or if, due to the infrequency and/or complexity of such care, results in other cases cannot be predicted with any degree of accuracy.
4. Is intended or is likely to create false or unjustified expectations of favorable results.
5. Contains a representation or statement of opinion as to the superior quality of professional services which is not susceptible to verification to the public or contains a statement representing that the member possesses skills or provides services superior to those of other physicians with similar training unless such representation can be factually substantiated.
6. Appeals primarily to a layperson's fears, anxieties, or similar emotions.
7. Contains, in reference to any matter material to a patient's decision to utilize a member's services, a representation of fact or implication that is likely to cause an ordinary prudent person to misunderstand or be deceived, or fails to contain reasonable warnings or disclosures necessary to make a representation or implication not deceptive.
8. Contains a prediction of future success or guarantees that satisfaction or a cure will result from the performance of the member's services.
9. States or implies that a member is a certified specialist unless he is certified by a board recognized by the American Board of Medical Specialties.
10. Concerns illegal transactions.
11. Is not identified as a paid advertisement or solicitation unless it is apparent from the context that it is a paid announcement or advertisement.
12. Relates to professional fees other than:
    (a) A statement of the fixed fee charged for a specific professional service, provided that the description of such service would not be misunderstood or be deceptive and that the statement indicates whether additional fees may be incurred for related professional services which may be required in individual cases, and
    (b) A statement of the range of fees for specifically described professional services, provided that there is reasonable disclosure of relevant variables and considerations affecting fees so that the statement would not be misunderstood or be deceptive, including, without limitation, an indication whether additional fees may be incurred for related professional services which may be required in individual cases.
13. Is intended or is likely to attract patients by use of puffery or exaggerated claims.

F. He performs an unjustified surgical operation or a surgical operation that is not calculated to improve or benefit the patient.

G. He practices or advertises under a trade name which is false, fraudulent, deceptive or misleading.

H. He performs a surgical operation or operations (except on patients whose chances of recovery would be prejudiced by removal to another hospital) under circumstances in which the responsibility for diagnosis or care of the patient is delegated to another who is not qualified to undertake it.

I. He participates in a charity raffle or other fund raising event in which the prize is any surgical operation and the member agrees to perform such operation.

J. He exhibits unprofessional conduct as defined in the *General or Specific Principles* of this Code.

II. Advertising

A. Subject to the limitations of *Article I, Section E*, a member may advertise his services through public communications media such as professional announcements, telephone and medical directories, and broadcast media. The following are examples of the types of useful information that could be included in ethical advertising. The list is illustrative and should not be interpreted as excluding other relevant information consistent with the ethical guidelines established herein.

1. A statement of addresses and telephone numbers of the member's offices.
2. A statement of office hours regularly maintained by the member.
3. A statement of language, other than English, fluently spoken by the physician or a person in the physician's office.
4. A statement as to specialty board certification or a statement that the physician limits his practice to specific fields.
5. A statement that the member provides services under specified private or public insurance plans or health care plans.
6. A statement of names of schools and postgraduate clinical training programs from which the member has graduated together with the degrees received.
7. A listing of the member's publications in educational journals.
8. A statement of teaching positions currently or formerly held by the member together with pertinent dates.
9. A statement of the member's affiliations with hospitals or clinics.
10. A statement that the member regularly accepts installment payments of fees and/or credit cards.

B. A member shall not compensate or give anything of value directly or indirectly to a representative of the press, radio, or television or other communication medium in anticipation or return for recommending the member's services or for professional publicity. If a communication to the public results from a payment by a member, such as a payment to a public relations agent, this must be disclosed unless the nature, format or medium of the communication makes that fact apparent. A member may pay the reasonable cost of advertising permitted by this *Code*. A copy or record of an advertisement in its entirety shall be kept for one year after its dissemination. If the paid advertisement is communicated by television or radio, it shall be prerecorded and approved for broadcast by the member and a recording of the actual transmission shall be retained by the member for one year after its dissemination.

III. Solicitation

A. Solicitation means in-person communication to specific individuals to attract them as patients.

B. A member shall refrain from engaging in systematic verbal solicitation of patients in person, by telephone, or through agents.

C. A member shall not initiate contact with a prospective patient if he should know that the physical, emotional, or mental state or degree of education of the person solicited is such that the person could not exercise reasonable judgment in employing a plastic surgeon.

D. A member who has given unsolicited, in-person advice to a layperson that he should have medical or health care shall not accept employment resulting from that advice if:

1. The advice embodies or implies a statement or claim that is false, fraudulent, deceptive or misleading within the meaning of *Article I, Section E*.
2. The advice involves the use by the member of undue influence, coercion, duress, harrassment, intimidation, unwarranted promises of benefits, over-persuasion, overreaching, or pressure for immediate response.
3. Any non-patient has given the member notice that he does not want to receive communication from the member.

IV. Enforcement

Any member charged with a violation of any ethical standard set forth herein shall be subject to disciplinary measures, including censure, suspension or expulsion, as described in Article XVI of the Society's Bylaws.

*The masculine pronoun is used through the Code of Ethics to refer to both male and female physicians.

Abstracts in the
advertising
sections

RICHARD L. DAKIN, M.D.
1300 SO. [illegible] DRIVE
[illegible], CA [illegible]

The New England Journal of Medicine

Established in 1812 as The NEW ENGLAND JOURNAL OF MEDICINE AND SURGERY

VOLUME 299 AUGUST 31, 1978 NUMBER 9

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already ruled that bar associations may not restrain lawyers from advertising their fees (although they may regulate the manner in which it is done), it is unlikely that local medical societies could legally prevent physicians who wished to do so from advertising *their* fees in newspapers or elsewhere. Yet I can only hope that the practice does not become widespread, for it is easily abused and will not, in my opinion, do much to lower the cost of medical care. On balance, I believe that fee advertising is not in the best interests of the public or the medical profession, but I concede this to be a moot question that bears further consideration. At any rate, I am not inclined at present to include fee schedules in the directories that I am proposing. Patients interested in that information can easily check with physicians' offices before deciding on whom they wish to consult.

Commercial advertising, to attract patients with promises of special skills of cut-rate service, is most emphatically not what we need. Dissemination, under professional surveillance, of factual and detailed information about the availability of physicians and health services in each community is something else. That is a service the public has long needed, and now is the time for organized medicine to provide it.

Arnold S. Relman, M.D.

SOUNDING BOARDS

THE FEDERAL TRADE COMMISSION ENTERS A NEW ARENA: HEALTH SERVICES

In 1975, the Federal Trade Commission (FTC) commenced an investigation into four major health-related areas: AMA policy on physician advertising, control of health-provider supply, solo-practice physicians as inhibitors of HMO development, and the relative value scale (RVS) as a form of collusive fee setting. The current status of FTC activities in these four areas is variable, to some extent confidential, and represents a new interface between the federal government and the medical profession.

Physicians, justifiably concerned over rising costs and the need to emphasize quality of care at low cost, may wonder if it is appropriate for the FTC, created to protect the public from anticompetitive abuse by corporations, to conduct an investigation of a profession composed of thousands of individual practitioners. Is it acceptable, in an open society, and in the day of the "Sunshine Act," that the FTC should do much of its work in secret? What enables the FTC to consider medical practice as a business subject to market forces and government regulation? Are the active medical practitioners actually united in an organizational structure adequate to constitute a corporate threat to free competition, or act as a monopolistic provider? Will such an investigation and its adversary proceedings result in any improvement in the quality of medical care for patients, any lowering in its cost, any improvement in manpower supply, any upgrading in quality or any further advancement of medical research? As we pieced together the FTC's agenda in the health field, these and other fundamental questions regarding the Commission's underlying assumptions about health-care delivery became more evident. This paper is an attempt to assimilate what is known about the investigation and to analyze it in terms of these questions.

The Legal Authority

The FTC was created in 1940 by the Federal Trade Commission Act. Its primary function was to enforce Sections V and XII. Section V prohibits unfair methods of, or restrictions in, competition, as well as unfair or deceptive acts in trade. Section XII prohibits false advertising of foods, drugs, devices and cosmetics. The FTC was also to enforce Sections II, III and VII of the Clayton Act, prohibiting price discrimination, exclusive dealing, corporative acquisitions of stock and interlocking directorates. The FTC also has the power to enforce several other more narrowly defined laws, such as the Wood Products Labeling Act and the Fair Packaging and Labeling Act. In addition, the FTC can address Sherman Antitrust Act violations through its broad jurisdiction over unfair trade practices.[1]

The Commission is composed of five persons who are appointed by the President and confirmed by the Senate. No more than three of the five Commissioners may belong to the same political party. Their term is for seven years, each expiring in a different year.[2] At present, the Commission consists of two Democrats and three Republicans.

The FTC Staff is organized into the Bureau of Competition and the Bureau of Consumer Protection. These agencies conduct investigations under the FTC Act, using the subpoena power for witnesses and documents, access rights and the federal power to require companies to report periodically. The primary enforcement tool is the "Cease and Desist Order," enforceable under threat of civil penalties, court injunctions and contempt citations. The Commission can also use a consent order procedure to obviate litigation through negotiated settlement.[4]

The FTC also enacts trade regulations and industry guidelines, recommends Congressional legislation, and seeks to influence other government agencies.

Before 1975, it was assumed that the professions were exempt from antitrust considerations. In June of that year, the Supreme Court, writing in *Goldfarb v. Virginia State Bar* held that the "learned professions" were indeed subject to antitrust litigation. The case involved a class-action damage suit filed by Mr. Lewis Goldfarb against the Fairfax County and Virginia State Bar Association's fee schedule. This minimum-fee requirement, it was claimed, constituted price fixing in violation of antitrust laws. The court ruled that "professional exemption" from these laws was not adequate grounds for defense.[5] The FTC has used this ruling as justification for its investigation of the medical and dental professions. In 1976 the Commission voted to conduct an investigation of the health field, with one member dissenting.[6]

Interpretation of this history suggests that the FTC has never previously dealt with the medical profession in a major way. As an agency, the FTC has had very little experience of the intricate system that has evolved in an effort to maintain quality components in medical education and care. They have neither sought nor used any systematic physician input in this investigation, other than responses to accusatory statements, or the standard interrogatory procedures of the legal adversary process.

All members of the FTC are lawyers; not one is a physician, nor has any ever had any public role or demonstrable experience in health care, health manpower, health education or health-services regulation. Although the Supreme Court decision involved the practice of law, the Commission has chosen, instead of examining abuses in the legal profession, to turn its attention to the medical profession.

THE PURPOSE OF THE INVESTIGATION

Although one might argue that the Goldfarb case provides the FTC with a mandate to investigate price schedules in any profession that it might choose (legal, medical, clerical, teaching or architectural) it is not clear why a Supreme Court decision on alleged price fixing by lawyers should enable a federal commission to extend subpoena power into matters of medical-quality control, medical-school accreditation, the establishment of health-maintenance organizations and the entire area of health education, manpower supply and certification. In our opinion, this assumed mandate to investigate and thus to regulate the practice of medicine should be subjected to question at the highest judicial level.

At the same time, one may ask why the Commission has launched a large-scale investigation into an area largely unknown to its members. The official reply was provided recently by the new chairman, Mr. Michael Pertschuk. He noted that health care, largely a private enterprise in this country, has been affected by severe inflation. He stated, "...one possible way to control the seemingly uncontrollable health sector could be to treat it as a business and make it respond to the same marketplace influences as other American businesses and industries."[7] One may justifiably question the evidence upon which Mr. Pertschuk bases his assumption that physicians and dentists practice in response to "market forces."

Evidently, the FTC views health-cost inflation as due to lack of competition among physicians. Such a view appears to neglect the fact that the competitive market model does not always fit with the facts of medical-care delivery. Important inflationary factors are involved beyond the physician-fee structure, and involve both market aberrations and cost escalations peculiar to the medical system, uncontrolled by the physician provider. Examples are to be found in the increased public demand for services, insensitivity to pricing on the part of hospitals and patients because of third-party reimbursement, fraud in the operation of nursing homes and clinical laboratories and the overuse by physicians of expensive medical technology, as well as cost inflation due to the threat of malpractice litigation, and the construction of hospitals with reduplicated major services. Most importantly, the inflation of hospital costs has been predominant over the past two decades whereas physician fees have inflated at a slower rate, and now constitute only 20 per cent of total health expenditures.[8] Granting an urgent national need to examine the costs of medical care and ways to control them, the FTC investigation suffers a very severe limitation, by focusing its activity on "organized medicine," and thus having an effect only on the physician-fee components.

Despite these limitations, and armed with its subpoena power and the impressive muscle of a federal commission, the FTC has drawn the medical profession into the vortex of its investigation. Various voluntary medical agencies have been subpoenaed and forced to provide bits and pieces of information that the FTC hopes to assemble into some sort of meaningful matrix to establish the truth of its contention that there is anticompetitive activity among physicians, responsible as a major force for cost inflation of medical care in the United States.

Will the projected outcome of this activity result in any improvement in medical care, or any lowering of its cost? To answer these questions, we should review the several specific directions that the FTC investigation has taken.

THE AMA POLICY REGARDING PHYSICIAN ADVERTISING

Section V of the AMA *Principles of Medical Ethics* states that a physician should not solicit patients; the Judicial Council (1971) goes on to delineate this proscription, stating that "solicitation as used in the Principles means the attempt to obtain patients or patronage by persuasion or influence."[9]

In the fall of 1975, the FTC issued a formal complaint against the AMA and two local medical societies, contending that such a proscription is anticompetitive and violates the Federal Trade Commission Act.

The second part of the complaint challenges other provisions in the *Principles of Ethics* dealing with contractual arrangements between physicians and third parties. The relevant provisions are claimed by the complaint to restrict physicians in the following ways: physicians cannot bid for contracts with lay organizations; physicians and lay organizations must bill patients separately for their respective components of the services rendered; and physicians cannot enter into a partnership with other nonphysician health professionals.[10]

The Commission trial brief filed by the FTC contends that, taken together, these provisions are in violation of Section V of the Federal Trade Commission Act for three reasons. First of all, it claims consumers have been deprived of information pertinent to the selection of a physician. Secondly, the provisions restrain competition between doctors in the delivery of services. Thirdly, they serve to stabilize or fix the prices of physicians' services.[11]

The AMA's brief contends that the code of ethics is not subject to antitrust concerns because enforcement can only result in revocation of society membership. This penalty, it claims, has no economic consequence.[12]

The FTC trial process began in September, 1977. The outcome remains uncertain. The importance of the decision hinges on the FTC contention that in proscribing physician advertisement, the AMA *could potentially* be acting as an economically motivated trade association, rather than in the public interest. If the court accepts this allegation of potential wrongdoing, other aspects of the investigation will be taken more seriously. Even before the decision, there has recently been a tendency, in several quarters, for physicians or physician groups to start some move toward broader use of advertising.[13]

In an interpretation of these events, it appears that the Commission regards the proscription against advertising as arbitrary and contrary to the public interest. One cannot but expect that the FTC lawyers would understand more clearly why physicians have wanted to avoid advertising if they had, themselves, become aware of the extreme receptivity of suffering patients to any highly touted cure. This trend was especially noticeable during the period of flagrant hucksterism and quackery rampant in the United States 75 years ago, including such things as goat-gland transplants in the treatment of male impotence and, later, Krebiozen and Laetrile in the treatment of cancer. The proscription arose historically in an attempt to eradicate commercial abuse. Even if we accept the possibility that advertising would lower the cost of medical services, is it possible or credible, against this historical background, to accept the FTC contention that medical care will thereby be improved? As physician advertising begins to appear, both patients and physicians are entitled to inquire whether or not widespread advertising of physician services, potent drugs, new remedies, cancer cures and physician corporations will actually improve medical care. Such advertising will certainly add a new expense to the mounting cost of American medicine. Taxpayers and consumers are entitled to ask why, and by what social or economic mechanism, such advertising would improve medical care or lower its cost.

Control over Health-Care-Provider Supply

On April 13, 1976, the Bureau of Competition of the FTC opened a second major area of investigation in the health-services area. The intent was to determine whether or not organized medicine had the right or *potential ability* to control the supply of health-care providers — i.e., physicians. This investigation was focused on three questions: Can the AMA control the medical-school accreditation process? Do physician specialty societies set up jurisdictional limitations in an arbitrary or anticompetitive way? Are arbitrary limitations established by the medical profession on the number or practice of allied health-care professionals?

Accreditation of medical schools is the function of the Liaison Committee on Medical Education (LCME). Six of the 15 members of this body are appointed by the American Association of Medical Colleges (AAMC), two are elected by the prior LCME membership, and one is a government representative. By law, this body must petition the Office of Education (DHEW) every four years for recognition. There is broad representation on the LCME, including persons not concerned with the everyday "competitive" practice of medicine. The orientation is more toward university regulation than it is toward the "medical marketplace."

The Bureau of Competition advised the Office of Education to deny the LCME its recognition in March, 1977, basing its reasoning on a perceived conflict of interest between the AMA with the public responsibility of the LCME, on the one hand, and the "commercial self interest" of the AMA (as phrased by the FTC), on the other.

The Bureau of Competition claimed that the AMA, although clearly a professional society with scientific interests, also acted as a trade association representing the profession's interests in economic and political matters. The Bureau contended that since the AMA directly administered the LCME every other year, contributed half its funding and appointed six of its members, it could, theoretically, heavily influence its decision-making. This, the Bureau of Competition claimed, did not satisfy the Office of Education's criteria regarding autonomy and avoidance of conflict of interest.[14] The Commissioner of Education did not withdraw recognition, but did limit it to two years instead of four. In addition, he directed the LCME to report in one year's time on progress toward broadening its representation.

There is not space here to review familiar history of the rise and fall of the proprietary medical schools, and the effect of the Flexner Report on them between 1915 and 1925. This history is as essential to any realistic understanding of medical-school accreditation as the history of the corporate monopolies and the "robber barons" of the 19th century would be to any understanding of the Sherman Antitrust Act. Most physicians will find it discouraging that a federal commission is beginning new initiatives directed against medical-school accreditation. Even if it were acknowledged that a withdrawal of physician overview of educational excellence or accreditation of medical schools might reduce the cost of medical education, by opening the country to a new set of low-cost educational enterprises, do we believe that this step would improve the quality of medical education and thus of medical care? If physicians and educators are not the persons to establish curricula and tests of achievement in the biomedical sciences and practice, who should do it? And how should such persons be appointed?

FTC investigation into board certification partakes of the same background. The Bureau of Competition is exploring specialty-board certification policy and practices, to determine if arbitrary market divisions exist in the practice of medicine either by agreement or by predatory conduct within a defined specialty. The Bureau endeavors to demonstrate that barriers to entry are based on an anticompetitive economic motive, in addition to the stated purpose of quality maintenance. To prove this contention the FTC would be required to determine that board certification has an economic effect in the sense that some physicians fully able to provide medical services are prevented from doing so. In addition, the FTC would be required to demonstrate that the certification process was administered in an unfair or discriminatory manner, for the direct benefit of the examining agency.

It seems that the Bureau of Competition will indeed discover that examination and certification are anticompetitive. Examinations are tests of achievement, and by their very nature they establish criteria for entering practice. They are intended somehow to inhibit practice entry into that specialty, for those who fail them. And yet they do not overrule state licensure, and in this sense the board examination procedure falls short on both scores: meeting their social objectives on the one hand, and fulfilling the definition of "anticompetitive" on the other!

The social and economic effect of a demonstration by the FTC that examinations are anticompetitive is severely limited by the fact that any process of examination for licensure, by its very nature, constitutes an anticompetitive barrier. But only to the extent that failure in an American board examination denies the right to practice is the failed candidate being denied the right to compete. Any criterion established to assure high-quality practice on the basis of educational credentials, as a condition for public service, is in itself restrictive and anticompetitive. If this activity (specialty-board certification), conducted by the medical profession, is declared economically abusive by the FTC, the Commission would then be forced to direct its attention to the bar examinations in all 50 states, and to the innumerable licensing and enabling bodies scattered throughout our society, ranging from aircraft pilots to journeyman plumbers.

Because of concern over all aspects of graduate medical education and board certification, a new commission was appointed in the autumn of 1976, within the framework of DHEW, entitled the "Graduate Medical Education National Advisory Commission." This body was to report to the Assistant Secretary for Health and Scientific Affairs on the whole fabric of specialty and geographic distribution of physicians, their production, training and graduate credentialing. In view of this impressive effort by DHEW, is it economically justifiable for another branch of the government to undertake the expense of an entirely new and independent investigation in precisely the same area?

Physician Groups and Health Maintenance Organizations (HMO)

A third major area of investigation has been the relation between physician groups and HMO's. The issue is whether HMO's are inhibited in their growth by anticompetitive behavior of other physicians or groups. The assistant director of the Bureau of Competition, Alan K. Palmer, states, "HMO and similar prepaid health plans have not grown to the extent that their backers had hoped. And there is evidence that at least one reason for this is that they have been the victims of anticompetitive conduct engaged in by practitioners of fee-for-service medicine who for various reasons oppose the HMO concept."[15]

Whether or not proof of such anticompetitive behavior exists is not the main issue. Clearly, if such behavior does exist and is proved to be illegal, it should be prosecuted. The more interesting concern is the advocacy role that the FTC has, perhaps inadvertently, adopted here. Is it an appropriate role for the FTC to provide governmental support to one particular mode of health-service provision? Has the FTC carried out the necesary research to determine that HMO's are an ideal form of medical-service provision?

In point of fact, the reasons for slow development of HMO nationally are well defined. The federal government has assisted in their development by providing some very limited start-up capital, but has hindered their growth by legislative requirements for comprehensive benefits and a prolonged open enrollment period. This step forces any new HMO to compete on the open market against insurers with substantially lower rates that are permitted to provide much narrower coverage, and to avoid bad-risk patient enrollment.[16] The FTC has ignored this intervention into competitive market forces, while pointing a finger toward physicians as the culprits. On the basis of available evidence, it seems unrealistic to claim a large-scale or systematic conspiracy on the part of physicians against HMO's. Merely to uncover isolated instances of local physician groups seeking to inhibit HMO growth scarcely proves the contention that this activity has appreciably contributed to their slow growth nationally.

The threat of federal investigation and FTC orders could modify the very competitive forces that HMO's should survive and overcome if they are to establish themselves as a viable component of the nation's health-care system.

Physician Influence over Third-Party Reimbursement Plans

The fourth major area of the FTC investigation focuses on the issue of whether or not physician influence over Blue Cross and Blue Shield organizations serves to modify the normal insurance-industry incentive to minimize costs. Since Blue Cross and Blue Shield plans represent about half the private health-insurance industry, such an effect could have serious inflationary consequences. Once again the FTC is looking for evidence of physician conspiracy because that is the kind of economic abuse it is empowered to deal with, despite the fact that physician fees are not the major factor in health-cost inflation, while other more important inflationary forces urgently demand attention.

Blue Cross plans reimburse health costs other than physician fees, such as hospitals, nursing homes and pharmaceuticals. Inflationary pressures are keenly felt from all those areas. Physicians individually make the management decisions that, in the aggregate, call forth goods and services purchased by Blue Cross, a form of inflation that fails to increase physician income by the conventional fee route. Furthermore, physicians have no control over the "patient mix" presenting for treatment, and in this sense they do not control costs of illness, either individual or aggregate. Just one ruptured aneurysm or severe burn, arriving for treatment at a health-service facility, will have far more effect on the total cost of the treatment of illness than the aggregate of the very large number of daily physician decisions concerning tests or treatment modes. As for collusion or conspiracy in this area, it hardly appears to be in the self-interest of physicians to engage in a conspiracy to inflate hospital costs. There is little evidence that Blue Cross plans have inflated physician-fee reimbursement, whereas Blue Shield plans have, by definition, played a major part in physician-fee regulation. In one particular state (Massachusetts) the Medical Society is currently suing Blue Shield for redress on the grounds that reimbursal rates have lagged behind the cost of living. Such a lawsuit hardly suggests prior collusion.

In testimony before Congress reported on March 23, 1978, the FTC chairman, Mr. Pertschuk, publicly stated that Blue Shield dominance by physician groups posed a conflict of interest, and suggested that new legislation, or action by the Commission, might be necessary to rectify the situation.[17] These statements were not accompanied by any hard data or recommendations, and they blurred public understanding of the distinction between physician fees and overall health costs. They were made in an attempt to influence the opinion of a Congressional legislative committee. They were among the first of public statements made by Mr. Pertschuk, after an investigation conducted largely in secret. To emerge from a semisecret investigation with a national press release seems an inappropriate way for a dignified federal agency to proceed.

The FTC has also investigated the use of the "relative value scale." These scales have been established in a number of areas of the country. When a unit value is assigned, physicians' services acquire a weighted value, which bears an established relation to other services. The FTC contends that such a method establishes a fixed-fee schedule. The FTC particularly objected when the relative value scale was developed by a physician group. The Bureau of Competition of the FTC has, to date, issued consent orders to prevent four specialty groups from employing relative value scales.[18]

In the view of some physicians, any relative value scale has appeared as an unwelcome standardization, imposed from without, and preventing increase of fees to meet living costs. The establishment of "reasonable and customary" fee schedules by third-party agencies has also appeared to act as a restraint. It appears to be a remarkable irony that the FTC now contends that such relative value scales are acting to increase physician income, and are adverse to cost containment.

The FTC has not objected to the establishment of relative value scales set up by third-party reimbursement groups. The Bureau of Competition evidently has concluded that a relative value scale established by an insurance plan, independently of systematic physician input, will not reflect physician self-interest. The consumer is entitled to ask whether such agencies, lacking detailed physician input, might not falsely inflate fees, as well as act as a downward regulator.

Regardless of this theoretical point, it appears in the public's best interest to maintain a system of relative value scales to control the inflation of physician fees. To destroy this safeguard in the name of cost containment could be remarkably counterproductive.

Summary and Conclusions

The FTC, a group of lawyers without any representation from physicians or consumers, has undertaken to examine certain aspects of the delivery of health services in the United States, acting under the rubric of a Supreme Court decision adverse to fee setting by lawyers. The FTC is investigating, in partial secrecy, four specific areas: physician advertising; medical-school accreditation; the relation between solo-practice physicians and group health-care systems; and the relation between physicians and third-party reimbursement plans. The FTC appears to assume that cost inflation in medicine is due to the anticompetitive behavior of physicians, as expressed through medical-school accreditation, specialty-board examination and certification, ethical bans on advertising, and the establishment of fee schedules by the relative value system. In all these areas, the Commission appears to contravene efforts of the medical profession to abate quackery, to monitor medical education, to establish competence standards for practitioners and, by the relative value scale, to protect the public from irresponsible fee inflation. The outcome of this investigation could jeopardize the quality of medical care in the United States, without any perceptible effect on its cost. From a procedural point of view, this activity of the FTC has two noteworthy features: partial secrecy and lack of medical consultation. It is understandable that in preparing an antitrust brief in the corporate field, some degree of secrecy is required during the initial assembly of evidence, prior to a trial. When applied to the examination of a practicing profession such as medicine, law, architecture, teaching or the clergy, such secrecy appears contrary to the constitutional tradition of an open society. Before the FTC holds further hearings in this connection, or releases further public statements or testimony before Congress, it would seem advisable than an advisory group be formed, to provide information and background for the investigation. It would appear wasteful and possibly foolhardy for a federal commission to spend several millions of dollars in an area far removed from its traditional expertise, without the aid of such an advisory group.

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ADVERTISING IN MEDICINE — A PHYSICIAN'S PERSPECTIVE

A campaign against the American Medical Association's bans on commercial advertising opened in December, 1975, when Mr. Alfred Dougherty, a deputy director in the Federal Trade Commission's (FTC) Bureau of Competition, held a news conference.[1] He said that advertising would create an informed public, beneficially affect prices and create competition.

The AMA subsequently explained that *advertising* is permitted when the effect is to inform (such as listing telephone numbers and office locations).[2] In contrast, *solicitation* is not permitted because the form and intent are self-serving (as in testimonials and other self-laudatory "commercials"). Then, on June 27, 1977, the United States Supreme Court decided that a lawyer may advertise the price of routine services in a newspaper.[3] The Court said that it expects that the Bar will have a special part to play in assuring that advertising by attorneys "flows both freely and cleanly" and further said that there may be "reasonable restrictions on the time, place and manner of advertising." Announcing fees appears to differ little from announcing a new place of business or a telephone listing; reasonable restrictions appear to imply that advertising may be regulated to prevent solicitation.

In September, 1977, the FTC brought an antitrust suit against the AMA. It charged that the AMA "takes the law into its own hands by promoting ethical standards on advertising for its own members."[4] Apparently, the FTC's belief in the benefits of any kind of advertising and the FTC's desire to control the costs of medical care through antitrust litigation[5] did not coincide with the AMA distinctions and the Supreme Court's implicit restrictions on advertising.

To help understand the conflict better, this paper will analyze the functions of commercial advertising (i.e., solicitation), will observe whether competition exists now in the medical profession in the absence of "commercials" and will note whether professional bans on commercial advertising have purposes other than the self-serving purposes projected onto the profession by the FTC.

The Functions of Commercial Advertising

Commercial advertising is primarily and legitimately an attempt to gather business for one's self. If it results in destroying one's competition, the attempt is just more successful than usual. A company in a competitive industry like processed foods or textiles and apparel certainly does advertise and indeed may fail without advertising. But the competition exists before the advertising, and prices are determined by the reality of the competition itself rather than by any imaginative announcement of the product and its cost. Even when competition is marginal, as in concentrated industries like rubber goods, electrical products and oil, advertising not only persists but is massive and may effectively obliterate small competitors. Finally, franchised public utilities, despite having no competition, budget generously for commercial advertising.

One may conclude that the function of commercial advertising in competitive industries is survival and in noncompetitive industries is protection of a corporate image and preservation of market power. In either instance, the price of the product to the consumer must bear the cost of the "commercials." Commercial advertising thus appears to be a sometimes costly manifestation of commerce in general, rather than being informative or creative of competition in particular.

PROFESSIONAL COMPETITION

Commenting on the absence of commercial advertising in medicine, the FTC's Mr. Dougherty said, "The Principles [of Medical Ethics] put forth a message that competition, whether it be in price or service is somehow unethical among doctors."[5] Since this message is *not* contained in the *Principles of Medical Ethics* one must see if the FTC's charge applies to the real world of medicine by observing the medical marketplace for evidence of competition or its absence. If competition exists in a profession it would be in timeliness, personalization, expertise and price of service. And if competition is present in the medical profession, how and why does it differ from commercial competition?

Timeliness, Personalization and Expertise

Any doctor who furnishes a poor service to his patients or to consulting physicians soon finds that competition exists in medicine — his patients go, or are sent, elsewhere. The public can judge professional competition in timeliness and personalization of care and may react accordingly. Medical expertise, on the other hand, can best be judged by medical experts and is guaranteed, as much as possible, by the excellence of medical schools and their standards for admission, by state licensure controls, by in-hospital committee controls and by professional associations. Commercial advertising could not exert similar controls on any of these quality aspects of professional service and would, therefore, be superfluous for all but self-serving purposes.

Price Competition

Prices are another and legitimate way in which professionals compete. Price competition for physicians' services still exists, since the public is aware of the cost of such services. For example, increases in professional fees have been much less than the increases in price of the more fully insured hospital bed.[6]

Price competition for a hospital bed is weak because private and government insurance programs have resulted in coverage of about 90 per cent of all hospital bills. As hospital services have appeared relatively "free," demand for care has been skewed into the hospital, where out-of-pocket costs have been the least; cost-price inflation has ensued to meet the demand.[7] When the patient did not need to ask the price, hospital competition was shifted to fulfilling his desire for comfort and the best quality in diagnostic and therapeutic services. In the end, the public bought a medical product more expensive and complex than it might have desired if it had felt the cost — a cost hidden by powerful tax subsidies for health fringe benefits. It is curious that the FTC thinks commercial advertising can affect this classic demand inflation in some beneficial way when "commercials" are intended to increase demand and demand, itself, has no visible limits if the patient is not aware of the cost.

Price Advertising

If price competition is proper and exists among medical practitioners, advertising prices would seem as proper as publishing one's place of business or telephone number. One can therefore agree with the United States Supreme Court decision. The problem left for the profession is to determine and implement what the Court meant by reasonable restrictions on "time, place and manner," so that price advertising will not become improper commercial solicitation. For example, would a 5-by-5-cm column in a local newspaper run for three days be proper but television coverage of the same material running indefinitely be improper? Who should write the guidelines and enforce the regulations?

Although the United States Supreme Court has given the responsibility of regulating professional advertising to the states, the ramifications for law and medicine differ. The legal profession is regulated by individual state supreme courts having strong constitutional prerogatives. Since medicine has no similar constitutional counterpart, it is likely that states will give regulation of advertising to agencies established for other purposes. In any event, the power of some state agency will be necessary to write regulations and monitor advertising since a professional society doing the same thing would probably be viewed (by the FTC and others) as a trade-association conspiracy. The medical profession should work with state legislators to devise appropriate mechanisms to regulate and oversee professional advertising.

Commercial vs. Professional Enterprise

Why should there be restrictions on advertising in a profession if commercial enterprise is not similarly restricted from solicitation? First of all, one must understand the different goals of commercial and professional enterprise and the practical reasons why these different goals are prescribed by the public.

Commercial enterprise deals with buying and selling goods, and the primary goal is to serve the economic interests of the entrepreneur or the enterprise; public service is secondary. As long as commercial enterprise is perceived as the most efficient way to sell and service ordinary goods, public policy condones the primarily self-serving methods of commerce. Solicitation, though self-serving, is therefore tolerated in commercial enterprise.

In contrast, professional enterprise has the primary goal of serving the public. Physicians are professionals not because of some salable expertise but rather by "professing" always to hold their patients' interests first.[8] For practical implementation of this policy, laws and ethics limit a physician's economic gain to reimbursement for the services that he renders. Profits are condemned by statutes that prohibit various forms of fee-splitting, lest patients, instead of services, become the commodity sold in the medical marketplace. Solicitation has been disdained for professional enterprise since it would be incompatible with the profession's goal of serving people without profit.

A doctor may pervert the professional relation with his patient into a commercial relation by making a profit (i.e., payment contigent on something other than the services that he has delivered), and by gaining power to manipulate the patient's health care.[9] For example, a profit may be turned when a doctor accepts an "incentive" payment from a consultant (a "split fee") or from an HMO company (a "bonus reward") contingent on how much, or from whom, care is ordered. And power over the patient is manifest in either instance since the patient can be sold to the best bidder. It is logical to expect entrepreneurs who might sell their patients like ordinary commodities in a commercialized medical marketplace to opt for solicitation as a means of gaining business and manipulating patient care for a profit. It is logical, as well, for the FTC to push solicitation when it confuses conventional commercial enterprise with competition.

A Prediction

What might happen to the nature and form of medicine if commercial solicitation is not restricted or is actually imposed as the result of activities by the FTC? Large sums of money would be necessary to participate in solicitation for a share of the market. Consortiums of providers (hospitals, physicians and so forth) and insurers could best develop the financial resources needed. Some people see the HMO "alternative" as the ideal mechanism to form a consortium by the ability of HMO's to forge firm financial links and similar financial interests among providers and between providers and insurers. Surviving HMO consortiums would have power to obliterate their old or new rivals by solicitation and would have power to manipulate public franchising agencies for preservation or expansion of their share of the market. The counterforce to such commercial power in the medical marketplace would no doubt appear to be government regulation of medical consortiums as public utilities.

The pitfalls and ultimate public expense of using commercial enterprise to deliver medical care is beyond the scope of this paper. But one must carefully calculate the overt and hidden price to be paid both in dollars and in quality if utility-style regulation is used as a counterforce to a commercial consortium's power, or costs are transferred from the consortium to the public by queuing, or industrial action by organized personnel in an essential "industry" paralyzes delivery of services. One should also note the increased use of commercial rhetoric (market, franchise, industry, profit and so forth) that accurately characterizes the attempt to replace the *professional* contract between patient and doctor with a *commercial* contract between "buyer of care" and an HMO-type insurance company. If the substitution is successful, government, corporate and labor bureaucracies — masquerading as the "buyers of care" — will have acquired a powerful contractual "handle" with which to manipulate medicine for the goal of decreasing their own costs. The real patient will be left to bargain for quality of care from a company doctor who has the same financial interests as the "buyers" and insurer to decrease spending dollars from a fixed budget. Solicitation to manipulate the "customers" further — for expansion, for profit or for acceptance of a consortium being the best-of-all-possible medical worlds — is a predictable consequence of commercial medicine.

PROFESSIONAL BANS ON COMMERCIAL ADVERTISING

How, in contrast, do professional bans on commercial advertising protect the public from manipulation? For one thing, commercial advertising seeks to woo a public lacking the expertise to judge professional competence. Professional controls (state licensure, hospital committees, professional societies and so forth) may make errors, but commercial advertising would not correct them; errors would more probably be enhanced by "commercials" when one considers that physicians wishing to solicit have historically been unable to compete professionally through their own incompetence in either timeliness, personalization or expertise of service. Secondly, not one dollar spent on solicitation is spent on health care. Solicitation is, by its very nature, self-serving and in no way can be called equivalent to public-service announcements to vaccinate, stop smoking, drive more slowly and so forth. Thirdly, the function of commercial advertising as an attempt to overcome competition and preserve monopoly would conflict with the public's desire for a large number of providers from whom to choose care.

CONCLUSIONS

Self-serving commercial solicitation can be distinguished from professional advertising, which informs the public as by advertising place of business and prices, and can be distinguished from public-service announcements. The attempt of the FTC to impose on medicine a legal requirement to permit commercial solicitation would not create an informed public or produce competition but would hasten a change from professional to commercial enterprise for delivering medical services. A choice between professional and commercial enterprise for medicine becomes *either* a choice of wages for services delivered and professional competition *or* a choice of profits and consortiums grappling for market power through politics and the mass media. Since solicitation is only intended to create, enhance or preserve commercial profits and market power, it is not surprising that solicitation is absent in a profession dedicated to compensation only for medical services and dedicated to freedom of the patient from being manipulated like an ordinary commodity.

The medical profession should work with state legislators to devise appropriate mechanisms to regulate and oversee professional advertising so that problems from solicitation can be avoided.

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MASSACHUSETTS MEDICAL SOCIETY

DEATHS

OCKERT — Raymond George Ockert, M.D., of Mansfield, died on October 1, 1977. He was in his 70th year.

Dr. Ochert received his degree from Tufts College Medical School in 1935 and served with the Navy Medical Corps during World War II. He was a member of the American Medical Association.

He is survived by his wife, a daughter, two brothers and a sister.

OUELLETTE — Sister Mary Leo Cecilia Ouellette, M.D., of Waltham, died on December 12, 1977. She was in her 62d year.

Sister Mary Leo received her degree from Marquette University School of Medicine in 1949. She established the Torembi Mission Hospital in New Guinea and formerly served as administrator of the Maristhill Nursing Home. She was a member of the American Medical Association.

She is survived by her mother, eight brothers and two sisters.

PARKER — Stanley Gilbert Parker, M.D., of Cataumet, died on October 29, 1977. He was in his 84th year.

Dr. Parker received his degree from Middlesex University School of Medicine in 1942 and was a member of the American Medical Association.

He is survived by his wife, two sons and a sister.

PATTERSON — Robert Patterson, M.D., of Wellesley, died on November 23, 1977. He was in his 59th year.

Dr. Patterson received his degree from Kansas City University of Physicians and Surgeons in 1943 and was a member of the American Medical Association.

He is survived by his wife, a daughter and a sister.

PELLETIER — Valmore Alexis Pelletier, M.D., of Norwood, died on August 6, 1977. He was in his 77th year.

Dr. Pelletier received his degree from Harvard Medical School in 1926 and was a member of the American Medical Association.

PEPI — John Francis Pepi, M.D., of Scottsdale, Arizona, died on November 13, 1977. He was in his 68th year.

Dr. Pepi received his degree from Middlesex University School of Medicine in 1934 and served with the Army Medical Corps during World War II. He was medical director of Deer Island House of Correction and a member of the American Medical Association.

He is survived by his wife, two sons and a brother.

POPOLI — Alphonse Francis Popoli, M.D., of Westfield, died on October 30, 1977. He was in his 69th year.

Dr. Popoli received his degree from Georgetown University School of Medicine in 1935. He was a member of the American College of Obstetricians and Gynecologists and the American Medical Association.

He is survived by his wife, four sons, a brother and two sisters, and six grandchildren.

RABEN — Maurice Solomon Raben, M.D., of Waban, died on September 19, 1977. He was in his 63d year.

Dr. Raben received his degree from New York University School of Medicine in 1941 and served with the Army Medical Corps during World War II. He was formerly senior physician and professor of medicine at Tufts–New England Medical Center. He was a member of the American Society for Clinical Investigation and the Endocrine Society.

He is survived by his wife, two sons, his mother and a sister.

RICE — John Evarts Rice, M.D., of Worcester, died on December 28, 1977. He was in his 97th year.

Dr. Rice received his degree from Harvard Medical School in 1907. He was a member of the American Academy of Ophthalmology and Otolaryngology, the American Medical Association and a 50-year member of the Massachusetts Medical Society.

He is survived by three sons, 11 grandchildren and 11 great-grandchildren.

RICHARDSON — Guy Lewis Richardson, M.D., of Haverhill, died on September 7, 1977. He was in his 83d year.

Dr. Richardson received his degree from Columbia University College of Physicians and Surgeons in 1920 and served with the Army Medical Corps during World War I. He was formerly chairman of the Haverhill Board of Health. He was a member of the American College of Surgeons, the American Medical Association and a 50-year member of the Massachusetts Medical Society.

He is survived by his wife, two daughters and a son, and a brother.

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SPECIAL ARTICLE

YELLOW PROFESSIONALISM

Advertising by Physicians in the Yellow Pages

Julia M. Reade, M.D., and Richard M. Ratzan, M.D.

Abstract We compared the specialty listings of physicians in the Yellow Pages of the 1983 Hartford, Connecticut, telephone book with the board certifications in specialties of the American Board of Medical Specialties as listed in the American Medical Association directory or the Marquis *Directory of Medical Specialists*. There were 1179 listings by 946 physicians under 61 specialty headings in the Yellow Pages. We found that a mean of 12 percent of "specialists" listed in the Yellow Pages were not board-certified in a specialty, although they had had ample opportunity to obtain board certification.

We conclude that specialty advertising in the Yellow Pages is potentially misleading to consumers and that member boards of the American Board of Medical Specialties should consider ways to diminish this possible misrepresentation. (N Engl J Med 1987; 316:1315-9.)

IN 1975 the Federal Trade Commission (FTC) successfully sued the American Medical Association (AMA), charging it with the unlawful restriction of advertising by its physician members. This suit and its attendant issues spawned a barrage of arguments over the benefits and evils of advertising.[1] Two of the more salient but less well-studied issues highlighted by this debate are the important areas of truth in advertising — i.e., how physicians represent themselves to the public — and the ethical conflict between a physician's right to advertise for commercial and professional gain and the right of the largely naive public to protection from misleading claims. Related questions include the following: Who can represent themselves to the public as specialists? Should this be a privilege open to all physicians with an interest in a particular area of medical practice, or is the designation of a specialty a private reserve, open only to physicians with training or certification in that specialty? Is the public a potential victim of self-styled and untrained specialists? Does the medical profession need to act to protect the public? A related issue (which we do not have the space to address here) is the difficulty we had

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— and which consumers would certainly have — in gaining access to verified and up-to-date information on physicians and their credentials.

Methods

Using the Yellow Pages of the 1983 Hartford, Connecticut, telephone directory,[7] we tabulated information on the 946 physicians who listed themselves under 1 or more of 61 specialty headings. We then used the 1982 (28th) edition of the AMA *Directory of Physicians*[8] to determine, for each physician listed in the Yellow Pages, the year of licensure, self-designated specialty, and board certification by the American Board of Medical Specialties (ABMS). Using the 1981 edition of the Marquis *Directory of Medical Specialists*,[9] we recorded data on the physicians listed in the Yellow Pages who were board-certified and who chose to be listed in the Marquis directory.

The main focus of our study was the identification, according to the specialty under which they were listed in the Yellow Pages, of the number of physicians without board certification from the corresponding ABMS specialty board (Table 1). We divided physicians without board certification (as confirmed by the AMA or Marquis directory) into two categories. The first consisted of physicians whose Connecticut M.D. licensure had been granted before a cutoff year calculated, according to individual ABMS specialty, in such a way that the physicians would have had ample time to have passed board-certification examinations and to have been included in the two directories. We described these physicians as "eligible." We chose a sufficient margin to allow for individual variations in careers, public health service, illness, lag time for board scores to reach the directories, and so forth. Since Connecticut M.D. licensure can be obtained only at the end of one's second postgraduate year, our use of this starting point added, for most physicians, two more years to our margin.

The second category, "recent graduates," consisted of physicians whose Connecticut M.D. licensure had been granted during or after the cutoff year. Therefore, the physicians in this group may not have had time to finish their training and pass their certifying examinations in order to be included in the AMA or Marquis directories. No physicians in our study represented "grandfather-clause" exceptions.

Results

There were 61 specialty headings in the 1983 Yellow Pages for Hartford, Connecticut; under these headings were 1179 individual listings by 946 physicians. Some physicians listed themselves under several headings — e.g., obstetrics–gynecology and obstetrics. Others listed themselves several times under the same specialty by using their names and corporate titles. There were 1014 listings for the 40 headings in the Yellow Pages that corresponded to ABMS specialty boards. Of the 1014 physicians listed, 119 (12 percent) were in our eligible category but were not board-certified (Table 1). The other 21 headings were non-ABMS specialties such as nutrition, psychosomatic medicine, hypnosis, adolescent medicine, and so forth.

We noted several apparent numerical discrepancies. Because physicians may designate themselves in the AMA directory according to 1 or 2 of 81 "practice specialties," there were many disparities between the listings in the Yellow Pages and those in the AMA directory. For example, whereas 152 physicians were listed under internal medicine in the Yellow Pages, 239 self-designated internists were listed in the AMA directory. Many subspecialists listed themselves under both internal medicine and a subspecialty heading in the AMA directory but only under the subspecialty heading in the Yellow Pages.

Also confusing were the specialties that had identical numbers of doctors in the Yellow Pages listings and the AMA directory but different numbers of uncertified physicians — e.g., allergy, cardiology, endocrinology, and dermatology. In fact, different doctors listed themselves in the two directories. For example, the three doctors who designated themselves as allergists in the AMA directory were all board-certified. However, they were not the same three doctors listed in the Yellow Pages, only one of whom was certified.

Adding even more to the confusion was the large number of physicians (165) listed in the Yellow Pages under specialty headings that do not have corresponding ABMS boards — e.g., nutrition, hypnotism, diabetes, and geriatrics. We attempted to assess the board certification of these physicians by looking at their certification rates in related ABMS specialties —

Table 1. Physicians in Hartford, Connecticut, Who Were "Eligible" for Board Certification but Had Not Received It and Were Listed in the Yellow Pages and the AMA Directory.*

Medical Specialty	Yellow Pages		AMA Directory	
	No. of physicians listed	No. (%) eligible but not certified	No. of physicians listed (self-designations)	No. (%) eligible but not certified
Internal medicine	152	28 (18)	239	26 (11)
Allergy–immunology	3	2 (67)	3	0 (0)
Cardiovascular medicine	52	8 (15)	52	5 (10)
Endocrinology	21	3 (14)	21	0 (0)
Gastroenterology	30	2 (7)	23	0 (0)
Hematology	16	3 (19)	15	0 (0)
Infectious disease	10	0 (0)	12	0 (0)
Nephrology	12	2 (17)	13	0 (0)
Pulmonary medicine	27	2 (7)	22	1 (5)
Rheumatology	15	1 (7)	12	0 (0)
Family practice	33	10 (30)	29	6 (21)
Preventive medicine	5	3 (60)	6	2 (33)
Neurology	20	0 (0)	24	0 (0)
Psychiatry	85	11 (13)	86	10 (12)
Child neurology	4	0 (0)	3	0 (0)
Child psychiatry	13	5 (38)	15	3 (20)
Pediatrics	70	12 (17)	75	8 (11)
Neonatal–perinatal medicine	2	0 (0)	6	0 (0)
Pediatric cardiology	2	0 (0)	4	0 (0)
Nuclear medicine	1	0 (0)	2	0 (0)
Clinical pathology	1	1 (100)	0	0 (0)
Physical medicine and rehabilitation	6	2 (33)	5	0 (0)
Radiology	50	1 (2)	32	1 (3)
Dermatology	24	3 (13)	24	2 (8)
Obstetrics–gynecology	81	1 (1)	88	1 (1)
Obstetrics–gynecology subspecialty	6	0 (0)	0	0 (0)
Ophthalmology	52	2 (4)	51	1 (2)
Otolaryngology	29	0 (0)	25	0 (0)
General surgery	51	1 (2)	63	3 (5)
Colorectal surgery	8	2 (25)	6	0 (0)
Neurosurgery	15	0 (0)	15	0 (0)
Orthopedic surgery	46	1 (2)	46	0 (0)
Plastic surgery	30	13 (43)	15	1 (7)
Thoracic surgery	16	0 (0)	14	0 (0)
Urologic surgery	23	0 (0)	23	0 (0)
Pediatric surgery	3	0 (0)	3	0 (0)
Totals	1014	119 (12)	1072	70 (7)

*See Methods for the definition of "eligible."

e.g., psychiatry for hypnotism, and endocrinology, pediatrics, and internal medicine for diabetes. We found that the percentage of eligible physicians without certification in these related ABMS specialties was 8.5 percent. This percentage was only slightly higher than the overall noncertification rate of 6.1 percent among eligible physicians who listed themselves under ABMS specialties. We therefore inferred that the physicians who chose to list themselves under noncertifiable specialties were not substantially different, with respect to their training, from physicians who listed themselves under certifiable specialties.

The surgical specialties, with two notable exceptions, had very low numbers of uncertified physicians. This may be related to hospital regulations, which often require surgeons to be board-certified to obtain hospital privileges. Of note, however, were the large proportions of uncertified physicians in plastic surgery and colorectal surgery. In the latter subspecialty, there were only eight physicians in the denominator in our calculations, which unfairly inflated the percentage. In plastic surgery, however, 43 percent of the 30 doctors who advertised themselves as specialists lacked certification.

The most striking finding was the existence of relatively high numbers of doctors under the specialty headings in the Yellow Pages who, although they were eligible for ABMS certification according to our definition, were not board-certified. We calculated that 18 percent of the internists listed had had the opportunity to become certified yet had not. Fifteen percent of the 52 cardiologists were uncertified. Likewise, 13 percent of the psychiatrists and 17 percent of the pediatricians were "eligible" but uncertified.

The percentages would have been even higher if we had not corrected for recent graduates. For instance, if we had included recent graduates in our calculations, 22 percent (vs. 15 percent) of the cardiologists would have been uncertified. With use of the same calculation, the rate of noncertification among those listed under child psychiatry would have risen from 38 to 62 percent. Although we tried to be conservative by tabulating eligible specialists only, it is legitimate to ask whether it is fair to the public to advertise oneself as a specialist in the Yellow Pages, thus implying, or at least suggesting, that one has the same specialist expertise as the specialists in the Yellow Pages who are board-certified.

DISCUSSION

Medical organizations in the United States have opposed advertising by their members since the inception of the AMA's first code of ethics in 1847. As the AMA noted at the time, "These are the ordinary practices of empirics, and are highly reprehensible in a regular physician."[5] Detractors of the code have argued that the relationship between doctor and patient is mercantile in nature and follows the laws of supply and demand; one observed, "This may be a humiliating view of our practical status in the community, but it is undoubtedly a true one."[6] Yet the prevailing view, at least among spokespersons for a profession attempting to consolidate power while competing with "irregular" practitioners, has been that advertising reflects poorly on physicians and their profession — a view held by organized medicine well into the mid 1970s.

After the FTC suit in 1975, the AMA revised its code of ethics, dropping all prohibitions against advertising (except advertising that is false or misleading), and eliminated its previous distinction between advertising and solicitation. Ironically, the second change may have done more to undermine consumer protection than to promote free speech. The definition of solicitation that was eliminated by the code included claims that "contain incorrect or incomplete facts, or representations, or implications that are likely to cause the average person to misunderstand or be deceived."[7] This emphasis on the average person's understanding has been all but forgotten in the FTC's wave of intended reform.

Indeed, as several authors have pointed out,[8,9] all advertising has the capacity to mislead, and it rarely informs in an impartial and complete manner. The physicians who pay for upper-case listings and advertising copy in the Yellow Pages are not educating the public about the arcana of medical care; rather, they are promoting themselves and their products in a lay directory. They are substituting "product differentiation" for "dissemination of information."[10] Some, we suspect, are intentionally confusing matters by equating the two.

There is little question that physicians perceive the Yellow Pages, if not as advertising, at least as an important source of new patients and self-referrals. One need only look at the number of lawsuits brought by physicians against the Yellow Pages for incorrect or incomplete listings.[11] In 1981 a dermatologist in Florida won $93,000 in damages against the Yellow Pages (in a decision that was reversed upon appeal) for an incorrect address listing; the physician claimed this sum as reimbursement for income lost as a result of lost referrals. In 1980 a psychiatrist in Oregon sued for $60,000 in damages because she was incorrectly listed as an osteopath. A gynecologist in Florida sued the Yellow Pages because his name had been omitted from the listings.

The prevalence of advertising by physicians in the Yellow Pages, although abhorred by many doctors, raises important questions concerning the opinions of health consumers about advertising by physicians in general and advertising in the Yellow Pages in particular.[12,13] In a telephone survey of 415 residents of Illinois, the respondents were divided almost equally in regard to their opinion about the propriety of advertising by physicians.[11] Among the group favoring such advertising, the most commonly cited reasons for their approval were that advertising would identify a physician's specialty and that it would help consumers find a physician. A national telephone survey of 1504 people revealed that 62 percent thought that advertising in telephone books or newspapers would help people choose a doctor.[15] The majority thought that advertising by physicians was ethical and would increase competition but that these advertisements would not be truthful or lead to lower fees.

* The local medical societies, stripped by the FTC action of any but the most perfunctory of regulatory powers, can only *suggest* to members that they adhere to advertising guidelines. The Hartford County Medical Association, which has a membership of more than 1500 physicians (almost 90 percent of the practicing physicians in Hartford County), recommends to its members that they list their names under no more than two specialty headings (Gordon JM: personal communication). Yet, as is evident from our data, these guidelines are only suggestions, and the Hartford County Medical Association apparently has no recourse against its members who choose not to follow them. The licensing board, the Yellow Pages, and the local medical societies do not exercise regulatory authority.

* Legally, physicians may practice in any specialty they choose, with or without training in that field. They may also describe themselves to the public as specialists — e.g., by listing themselves in the Yellow Pages under particular specialty headings — as long as they refrain from making false claims. The only risk that self-designated, uncertified specialists face is that if they are sued for malpractice in the self-designated specialty, they may be evaluated according to the minimum standards of that specialty.

which [illegible] high

At the heart of advertising by physicians in the Yellow Pages is the thorny question, Who can describe himself or herself to the public as a specialist? In the past, specialization was tantamount to a hobby. Physicians developed particular interests, incorporated them into their practices, and became, ipso facto, specialists. They restricted their practices to those areas and received referrals from peers in recognition of an informally developed expertise. Over the past few decades, however, board certification in many specialties has become a minimum credential, and it is generally associated with better jobs, higher pay scales, influence concerning third-party reimbursements, and more prestige.

Moreover, board certification is becoming ubiquitous.[16] In 1979, 78 percent of the 205,000 physicians who designated themselves as specialists were board-certified as compared with 65 percent in 1972.[17] Overall, there was a 153 percent rise in the number of board certifications awarded in the 1973–1978 period as compared with the 1964–1969 period.[17] In addition, there is a rising percentage of board-certified physicians among younger doctors, suggesting that recent graduates of training programs are largely responsible for the increasing proportion of practitioners who are board-certified.

Is it fair to make board certification a sine qua non for describing oneself to the public as a specialist, or is mere interest in a specialty sufficient qualification? This is not an easy question to answer in a free-market society, and it raises additional questions. For example, what constitutes a specialist? The profession has not reached a consensus on this question. It would be naive to argue that only board-certified physicians are qualified specialists. There are many eminently qualified uncertified specialists who helped to found or shape their fields of expertise. Although board certification does not guarantee competence, it does guarantee a minimum level of training and acquired knowledge and determines "whether candidates have received adequate preparation in accordance with established standards."[18]

Is it fair to restrict the practice of a specialty or the representation of oneself as a specialist to those who are certified or trained in that specialty? We would argue, in the public's interest, yes. Yet this is a point that raises an old and time-honored complaint from generalists — that they are being unfairly excluded from an area of practice that is professionally and legally within their purview. In 1929, the Committee on Specialties and the Propriety of Specialists Advertising, which was commissioned by the AMA, stated that the committee members' chief objection to specialists was that they "operate unfairly toward the general practitioner, in implying that he is incompetent to properly treat certain classes of diseases, and narrowing his field of practice."[19]

It is ethically untenable, in our opinion, to hold oneself out as a specialist or to offer specialty services without expertise in that specialty. Although such expertise probably best correlates with specific training in that specialty, the determination of such expertise is problematic at best and certainly should not, in every instance, be left to self-designation alone. The implied expertise inherent in listings under the specialty headings in the Yellow Pages certainly misleads many unwary consumers and makes such advertising ethically questionable.

Ironically, this restriction is seen as paternalistic by consumer advocates and restrictive (to free trade) by proponents of the FTC's position. We would argue that until the public is better educated about the process by which physicians receive credentials and has better access to information about doctors, it needs protection. We would also argue that no profession is without restricted entry — a safeguard intended to ensure a minimum of competence among its practitioners.

The Committee on Medical and Deportment Ethics of the Hartford County Medical Association has tried to address some of these issues by suggesting guidelines for advertising in the Yellow Pages. It has recommended that physicians limit themselves to no more than two specialty listings because "a) there are very few physicians who actually practice more than two specialties and b) so that the specialty headings retain their meaning" (Crombie HD: personal communication). However, the same committee recommended that professional designations such as A.B.I.M. (American Board of Internal Medicine), F.A.C.S. (Fellow of the American College of Surgeons), and F.A.C.C. (Fellow of the American College of Cardiologists) not be used because "these designations have meaning, for the most part, only within the medical community, and, thus, would not assist most persons in selecting a physician."

We would argue that it is these very credentials that provide the specialty headings with meaning and that the public assumes that physicians who are listed as specialists have these credentials. Despite Attanasio's unconvincing arguments against the adoption in Italy of a policy of including professional qualifications in advertisements for physicians,[20] we believe that the public would be able to use such information properly and, furthermore, that it is entitled to the opportunity to do so. Given the likelihood that the specialty headings in the Yellow Pages are being abused by a small percentage of physicians who tacitly mislead the public with their claims of specialty expertise, it would seem useful to differentiate trained and certified specialists from persons without those attributes. We do not mean to accuse all uncertified self-proclaimed specialists of being intentionally deceptive or inept. (Our study demonstrated that many physicians in the uncertified group were recent graduates or trainees.) However, a differentiation between certified and uncertified physicians would not only offer protection to the public from some unqualified specialists but would also protect qualified specialists — professionally and possibly economically — from their uncertified competitors.

Moreover, the Yellow Pages includes specialty headings for which there are no approved training programs or specialty-board certifications. What is one to make of physicians who list themselves under "Hypnosis" or "Nutrition"? How does one objectively assess a physician's training or expertise in these fields? Yet the Hartford Community Medical Association recommendations for advertising in the Yellow Pages and the AMA directory include similar categories of self-designated specialties.

Our society's current regulatory efforts regarding licensure, advertising, and specialization have not kept pace with the changing face of medicine. Members of the medical profession have a collective moral responsibility to address these concerns and to force themselves to make the necessary difficult choices. We must face the realization that not only does the public suffer from inconsistent applications and definitions of standards, but ultimately, our professional credibility is at stake.

We are indebted to Joseph M. Healey, Jr., J.D., Associate Professor of Community Medicine and Health Care, and Margaret G.E. Peterson, Ph.D., Assistant Director, Biostatistics Research Center, University of Connecticut Health Center, and to Robert A. Duncan, M.P.H., University of Connecticut School of Medicine, for invaluable assistance.

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Guest Editorial

Plastic Surgery and the FTC

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Society of Plastic and
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● In the August 1978 issue of the *New England Journal of Medicine* (Volume 299, Number 9, Page 478, 1978), Joseph C. Avellone, M. D., and Francis D. Moore, M. D., carefully outlined the development of the Federal Trade Commission's foray into the medical field. While discussing four areas of involvement (i.e., relative value fee scales, AMA policy on physician advertising, control of health-provider supply, and solo-practice physicians as inhibitors of HMO development), the authors remarked that much of the FTC's activity has been veiled in secrecy and enacted with a singular lack of medical consultation. As a result, at the FTC's insistence on abolishing ethical norms in advertising, we are in the process of regressing some 75 years to the days of the exploitive, tasteless, high pressure ads. Most of these are in California and in the field of cosmetic surgery, though the practice is slowly metastasizing.

Not mentioned by Dr. Avellone and Dr. Moore was the current investigation of the American Society of Plastic and Reconstructive Surgeons, Inc. (ASPRS) by the FTC. This may well be far more dangerous and damaging than any of the others because it is clear that the action against our Society and Journal is a direct challenge to quality medical care, which, if successful, would apply to any specialty society and any specialty journal.

ASPRS has been singled out as a "trial balloon" testing the FTC's theory that medical *costs can be lowered if the quality standards of medical care represented by board certification are lowered.* Specifically, the proposed complaint, as originally drafted by the FTC staff, states that ASPRS has violated the antitrust laws by "maintaining unduly high standards for plastic surgery." Our reliance on board certification as a standard of competence is alleged to restrain unfairly physicians who are not board certified or board trained from practicing plastic surgery. The FTC proposal would force ASPRS to virtually ignore board certification as an essential measure of a physician's ability to practice the specialty.

In addition, the FTC would require our Society to de-emphasize board certification as a measure of competency to perform plastic and reconstructive surgery whe[illegible] questioned about the qualifications of [illegible] physician to practice plastic surgery. This de-emphasis is designed to downgrade board certification and equate all physicians claiming competence in this field.

Finally, the proposed order would infringe upon the rights of the editor of our Journal, the *Journal of Plastic and Reconstructive Surgery*, to select which advertisements and announcements will appear in the Journal. It is particularly distressing that the FTC will interfere with our Journal and yet refuse even to investigate the flagrantly deceptive advertising of some self-styled plastic surgeons.

This action should be understood clearly for what it is—a venturesome and misguided effort by a lawyer-dominated bureaucracy to impose an untested theory in an attempt to lower costs in medical care. It also must be clearly pointed out that the victims of such a policy, if successful, would be our patients. They would be even more confused in trying to determine who is a competent plastic surgeon and who is simply calling himself a plastic surgeon, but in fact, may have little or no training or experience. The horrors inflicted on innocent victims by those who falsely profess competence in plastic surgery was reviewed

In addition, the FTC would require our Society to de-emphasize board certification as a measure of competency. . . .

Substantially the same material has recently appeared in the *New England Journal of Medicine*, but the editors believe that the importance of the subject, the timeliness of the article, and the stimulating form of its presentation justify presentation to the readers of *Surgical Rounds*.

last year on CBS's "60 Minutes."

One may ask how the FTC got into this field of medicine about which it is basically uninformed. The FTC was started in 1914 to protect the public against unfair competition in commerce. Its power has been expanded over the years to cover unfair and deceptive practices. And, just three years ago, Congress passed the 1975 FTC Improvements Act which greatly broadened the FTC's authority. Still, the so-called "learned professions" of medicine and law, for example, were generally considered to be beyond its jurisdiction until three recent Supreme Court decisions.

In the 1975 case of *Goldfarb v. Virginia State Bar*, a suit involving minimum fee schedules of attorneys, the Supreme Court held that the learned professions were covered by the Sherman Act and the fee schedules were abolished. Again, in 1975, in *Virginia Pharmacy Board v. Virginia Consumer Council*, the Supreme Court ruled that ethical restriction on price advertising by pharmacists violated the Sherman Act.

It is worth noting, however, that Mr. Justice Stewart, in his opinion in *Virginia Pharmacy*, cautioned against an interpretation of the law which would equate the commercial marketplace with the medical profession regarding advertising. He wrote:

The so-called "learned professions" of medicine and law . . . were generally considered to be beyond its jurisdiction.

> *. . . the legislature is not dealing with traders in commodities but with vital interest of public health and with the profession treating bodily ills and demanding different standards of conduct from those which are traditional in the competition of the marketplace. The community is concerned with the maintenance of professional standards which will insure not only competency in individual practitioners, but protection against those who would prey upon the public particularly susceptible to the imposition through alluring promises of physical release, and the community is concerned with providing safeguards, not only against deception but against practices which would tend to demoralize the profession by forcing its members into an unseemly rivalry which would enlarge the opportunities of the least scrupulous.*

Nevertheless, in June 1977, the Supreme Court went one step further in *Bates v. Arizona State Bar* when it struck down the Arizona Bar Association's efforts to restrain solicitous advertising by attorneys of routine legal services.

The FTC staff jumped on the bandwagon of government action against the professions. As Jonathan E. Gaines, Assistant Director, Bureau of Competition, Federal Trade Commission, stated before the American Society of Association Executives on February 10, 1978: "Neither the nature of an occupation nor its public service aspect is enough to warrant exemption" [from the Sherman Act or FTC Act]. This attitude has been clearly reflected by formal FTC complaints against the American Medical Association, the Connecticut State Medical Society, the New Haven County Medical Association, and the American Dental Association, challenging the ethical standards on advertising which discouraged solicitation of patients.

As noted above, the FTC's efforts to abolish or weaken ethical standards of professional advertising are being done in the name of lowering the cost of medical care. Has it succeeded? Not in California. The bill of one such cosmetic surgeon for advertising in the *Los Angeles Times* alone (not counting other newspaper advertisements or his radio or TV ads) amounted to $123,000 in one year. Who pays for this? Obviously, the patient. Is he paying less for services? Again, in California, the charges by advertising so-called "plastic surgeons" vary between 30% and 50% higher than those of the board certified plastic surgeons in that state. But even more serious is the fact that considerable restraint should be exercised, particularly in the field of cosmetic surgery where so many cases are not well-suited for any kind of surgery and should be turned down.

Why has the FTC focused its attack on plastic surgery? We really can't be sure. The FTC has carried out an exhaustive study of many specialty boards and specialty societies. We know that there has been a small number of complaints from those without board certification in our specialty that denial of membership in our Society and alleged lack of access to our Journal for advertisements and announcements constitute an unfair restraint of trade. Although we do require complete certified training for Candidate membership and board certification for Active membership, we do have an Associate membership which does not require board certification. Furthermore, for many years, our scientific meetings have been open to all licensed physicians, as have our seminars, teaching sessions, publications, videotapes, audiotapes, films, etc. Also, with the current trends in medical advertising, plastic surgery does have what might be called a "high visibility" even though most of our members spend most of their time in noncosmetic surgery. Finally, our specialty is very small and perhaps more vulnerable to the staggering costs of federal litigation.

The FTC's appetite for more power has been clearly demonstrated by its recent efforts to persuade Congress to pass yet another "FTC Improvements Act"—vintage 1978. The proposed law was known as House Bill 3816 and, fortunately, was defeated just before Congress adjourned. Had this bill passed, and it nearly did, having attracted little attention from the medical profession, there are four devastating provisions which would have gone into effect. The bill, as originally proposed, would have allowed:

- Jurisdiction over *individuals* as well as *non-profit organizations* (such as the specialty boards themselves);
- Imposition of fines and penalties by the FTC *outside* of the traditional judicial system of the United States;
- Seizure of assets by the FTC of any individual or organization *prior* to filing a complaint;
- Placing the budget of the FTC (its life blood) and review of any of its decisions *outside of the review of the President of the United States.*

In regard to the action against ASPRS, we have continued to negotiate with the FTC and, as yet, a formal "order" has not been issued. If it is issued in its present form, we feel that we will have to resist it vigorously, but we will need help. We have already instituted a $400 assessment of each of our members practicing in the United States. One-third of this was paid within two weeks of the date it was due, and 80% within two months. However, these funds will be insufficient for the cost of lengthy litigation. Many of our colleagues have expressed concern and offered financial support, which we do not intend to ask for unless we are forced into litigation. I am anxious to know of any other interest or support.

While the FTC is trying to lower standards of medical care, it is interesting to reflect upon what Chief Justice Burger has said in respect to the importance of competence among professionals, particularly those engaged in specialized services:

> *. . . one of the most serious problems facing our profession . . . is the professional competence of those lawyers who come into the courts. . . . (W)e should see to it that those lawyers that come into the courts have at least the minimum acceptable competence. We can profitably look at the steps our medical friends took nearly half a century ago. They recognized the need to train physicians and surgeons separately, even though that separation was not rigid or absolute. Until we establish special standards for the right to appear in the courts, independent of admission to the Bar generally, we will not solve our problem. The needs of a modern courtroom can be analogized roughly to the needs of the modern operating room of the surgeon. In each situation, special training and skills are not simply desirable, they are imperative in the public interest. To treat a bare Certificate of Admission to practice law as a passport to try any and every kind of case in any court makes no more sense than to say that a medical school degree qualifies the holder to perform every kind of surgery. Our protection is that the hospitals will not let them do so.***

The FTC's appetite for more power has been clearly demonstrated by its recent efforts to persuade Congress to pass yet another 'FTC Improvements Act"—vintage 1978.

Incompetence in the operating room or in any field of medicine is no less abhorrent. The victims, of course, are our patients, their lives, their appearance, and their ability to lead a normal existence. We feel this test case is of critical importance to all of medicine in that this ill-advised approach by the Federal Trade Commission has already done great harm and is very likely to do considerably more to our specialties, our carefully developed system of training, our specialty journals, and most importantly, to our patients. ● ●

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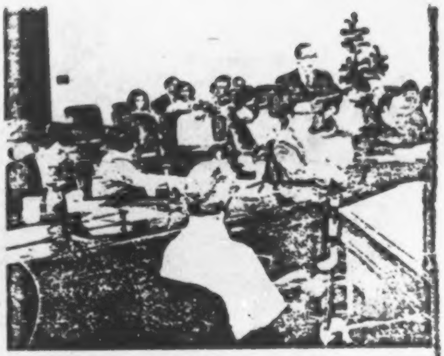
*Chief Justice Warren E. Burger to the American Bar Association, February 12, 1978.

medical world news COVER STORY

TRUSTBUSTERS PUSH INTO MEDICAL PICTURE



The year is 1997. Willy Wallbanger wakes one morning in intense pain.

Willy (*gasping, shakes his wife*). Sally, call Dr. Sterling. I got a terrible pain in my groin.

Sally. Oh, Willy, don't you remember? Dr. Sterling flunked his last re-examination. He forgot how to find the logarithm of pi. But I saw a billboard yesterday that says Dr. Bolus does gallbladder operations for only $100, if you sign up for his annual physicals.

Willy (*groaning*). I don't think it's my gallbladder. What does he charge for a diagnosis?

Sally. The billboard didn't say. But I saw an ad on TV. Dr. Benback diagnoses anything for $30. Wait a minute, I think he's a chiropractor. But he has hospital privileges.

Willy. I don't want a chiropractor. What does the newspaper say? Look in the "Doctor Review" section.

Sally. Here it is. Let's see. Their reviewer rates Dr. Firbush in this issue . . . Willy, go to him! He gets three stars. Oh . . . he's a psychiatrist.

Willy (*still groaning*). Call up the Consumer Action Group, Sally. Hurry. I gotta get some medical attention.

Sally. Hello? My husband's in terrible pain and he needs a doctor. Can you recommend one? A nurse-practitioner? No, he really would prefer a doctor. I know nurse-practitioners are competent, and they're usually cheaper, but we really want a physician. A bachelor of medicine? Can't you recommend a doctor? Yes, really. Thank you. (*She hangs up and turns to Willy, whose face is turning gray*). Willy, I got one. His name is Dr. Righthink, and he's very politically conscious.

Willy. Listen, Sally, I'm suspicious. Call the medical society.

Sally. Hello? Please, can you give me the name of a doctor in my area? You can't? Oh. Oh, I'm sorry to hear that.

Willy. What is it?

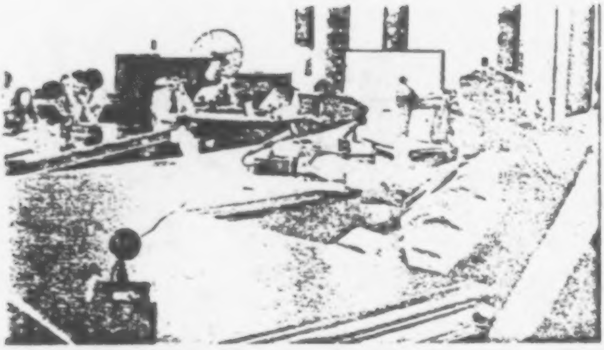
Sally. The medical society says it can't get involved because the Justice Department might charge it with antitrust activities. Their president is in jail for warning a doctor about overcharging a patient. But they suggest we contact the PSRO, and we can learn anything we want to about any doctor in town.

Willy. Sally, just take me to the hospital emergency room. And make sure the admitting physician isn't a podiatrist!

Farfetched? Conversations with people in government who are guiding the antitrust action against the medical profession paint a picture of medical practice remarkably like the above. The Federal Trade Commission's administrative "trial" of the American Medical Association and two Connecticut medical societies, which began September 7, and Sen. Edward M. Kennedy's (D-Mass.) joint hearings scheduled this month on health care competition have launched the medical profession into the unknown waters of antitrust law. It is now anyone's guess where it will beach.

Here are the best guesses of four people who ought to know: an FTC economist, who this past June organized the first national conference ever held on competition in health care; the deputy director of FTC's Bureau of Competition, which is suing the AMA; a top adviser on antitrust matters to HEW Secretary Joseph A. Califano Jr., who has some differences of opinion with FTC: and the staff assistant to Senator Kennedy, who organized the senator's scheduled medical antitrust hearings.

Warren Greenberg, 34, an economist, has been with the FTC for six years and involved in the economic aspects of competition in health care since early 1975. His master's dissertation at the University of Pennsylvania was on antitrust and industrial organization; his Ph.D. thesis in economics from Bryn Mawr College was on industrial mergers. He teaches a course on microeconomics at the University of Maryland.



In Washington, Judge Ernest G. Barnes listens as AMA lawyer Newton Minow (standing) attacks FTC's case against code of ethics that proscribes doctor advertising. If FTC wins—and courts agree—violations could result in $10,000-per-day fines.

Like most of the officials and staff at FTC, Greenberg wants to see a free, competitive market develop for health care services, not only among physicians but also between physicians and other health care professionals (such as nurse-practitioners). In its pure form, proposed by University of Chicago economist Milton Friedman, "We shouldn't have any licensing of physicians at all," says Greenberg. "I don't go that far." The FTC reluctantly accepts licensing, he says, but insists FTC's aim nevertheless is "to get the government out" of health care regulation—"as well as getting the AMA out of it." Self-regulation by physicians is anticompetitive on the face of it, Greenberg believes.

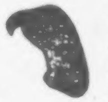
So long as licensing is necessary, however, Greenberg thinks licensing laws should not give physicians a market advantage over other health professions. That's anticompetitive, too. "People who elect to go to a nurse-practitioner to have their blood pressure taken, or for a simple cold, should be allowed to go," he says.

There will be costs to freeing physicians from the restrictions of AMA's code of ethics regarding advertising, Greenberg recognizes, but he thinks they will be worth it because consumers will finally be informed about what they can buy. Laws will forbid fraudulent ads, he feels. But there will probably be distasteful ads, marginally misleading ads, or ads that persuade patients to go to a less competent physician. "I don't like those types of ads either," he says. Informed consumers will be suspicious of them, he suggests.

"If a guy says, 'Get your brain surgery from me,' what would you do? You'd ask your family doctor what he thinks about him. You're going to be very, very careful. . . . I won't deny the fact that some people will go into brain surgery and have consequences that we all don't want. There will be costs—really serious costs—but the benefits are that we will know what the hell's going on in the medical marketplace. And some people will be directed toward a doctor who has an excellent record for surgical operations and is respected by his colleagues, who is very reticent now. Maybe we'll be able to make the good physicians busier." Greenberg recounts that physicians he has discussed this with tell him they will never advertise.

How will quality be maintained when AMA's code of ethics is made unenforceable? The medical marketplace will develop its own control mechanisms, Greenberg predicts. "A new restaurant opens. We know nothing about the quality, and it advertises a four-course dinner for $3. What happens? The market comes out with evaluation of restaurants. People who are employed by newspapers write that this restaurant—although it charges only $3—isn't worth 50¢. And then people don't go. And the same thing may very well happen in medicine. There may be medical guys who come out from Ralph Nader's group who say, 'This doctor sees people for $5 but he's just really terrible,' or maybe the insurance company will be a source of information, or maybe the AMA will start rating."

In the end, Greenberg says he really doesn't know what will happen when physicians are subjected to the economic pressures of the marketplace. But he is optimistic. "It will not make medical practice perfect or the quality of medicine all that better. There'll be some costs, maybe more room for the quack doctor. But there'll be some benefits. In my judgment, the benefits will outweigh the costs." Why does he think so? "Economic theory would suggest it is a step in the right direction."



The antitrust adviser to HEW Secretary Califano interviewed by MWN requests that her name not be mentioned in this article and notes that the views she expresses are strictly her own. However, she forcefully presents them to her boss whenever asked. And these days that is frequently.

She begins by asserting that the classic theory of supply and demand apparently espoused by FTC does not work for the health care "industry." "Even where there are three times as many physicians in one area as another, demand doesn't get satiated," she points out. "It continues to increase. And prices do not fall—they rise—just the reverse of what economic theory would tell you. There are others who still believe that if we flood the market with enough physicians, prices will drop. There is no evidence for this in any part of the country or in any specialty."

Noting that HEW's Office of Education turned down FTC's recommendation to disqualify the physician-controlled Liaison Committee for Medical Education as the govern-

continued

ment's certifying agent for medical school accreditation, she gives organized medicine a clean bill of health—at least since the early 1960s—for its role in increasing the number of competitors. "No one is stopping the supply of health care [professionals]," she says. "There is no conspiracy. We feel that a far more serious problem is maldistribution, not total supply."

On the suits by FTC and the Justice Department over relative value scales, she says, "I'm not sure where I come down . . . I don't know if it really is price fixing. I know at the federal level we need some mechanism of setting fees or payments. I'm not sure where the government is going to end up on that one. It's up to the courts."

Where HEW agrees with the antitrust actions of FTC, she says, is in the trustbusters' attempts to foster more competition between fee-for-service practice and Health Maintenance Organizations and to allow such health care professionals as nurse-practitioners to provide more services in competition with physicians. Also, getting more information to consumers is a good idea, she says.

"One of the things I've been pushing for is what I call local directories that will tell you that these are the hospitals in this area; these are their services; these are accredited by the joint commission and the state health department; their average daily charges are this, this, and this; they do or do not have open-heart surgery; they do or do not have nurseries; and these are their basic charges.

"Also, I'd like such a listing for all physicians and dentists, which says what their office hours are; what they are certified to do, if they are a specialty service; and what some of their average fees are. I also think the public should be informed when a physician has been disciplined by a PSRO for either overcharging, doing an unnecessary procedure, or being out of date. I think consumers should know who under Medicare takes assignment, and who doesn't; who's a Blue Shield participating doctor; who takes the full fee as full payment or who charges extra, perhaps."

Since she does not believe a true "market" exists in health care, she says she inclines personally toward "the regulatory theory." She would like, for example, "to go even further than our current licensing. I don't think it is good for the public to have someone licensed once. I would be more willing to attempt on a demonstration basis letting people take licensing exams who have not been to medical school and see if they can pass."

As for medical education, she says she is "not convinced that it doesn't need total reform, whether we don't need to produce an entirely different kind of mix. Why shouldn't we have a program that trains people at the college level—not postbaccalaureate but up to baccalaureate level—to do most of the primary care in the country, and use only the very sophisticated training for your very complicated stuff? You don't have to train people for seven years to take care of routine sore throats. Then I would say, 'Fine. Flood the market in primary care. Flood the market.' I think we need to change the entire pattern of delivering medical care. And it's not the way FTC would want to do it."

Whatever FTC's Greenberg says about not wanting to do away with licensing for physicians, Califano's antitrust adviser says, "If you really want to get a free market, you really have to go the Milton Friedman route. And I'm not sure that (a) FTC really understands the implications of doing that and what it was like in the pre-Flexner era, and (b) the American public really wants you to do that."

In antitrust actions aimed at health field, the pace quickens

June 1975. Supreme Court rules in *Goldfarb vs Virginia State Bar* that there is no "learned profession" exemption to Sherman Antitrust Act.

October 1975. Justice Department files suit against American Society of Anesthesiologists over their relative value guides.

December 1975. Federal Trade Commission issues a complaint against AMA, Connecticut State Medical Society, and New Haven County Medical Association, asserting medical code of ethics illegally prohibits physician advertising.

May 1977. Deputy director of FTC's Bureau of Competition Schwartz writes to U.S. Commissioner of Education Ernest L. Boyer asking him to reject the routine application for continued recognition of AMA-AAMC's Liaison Committee on Medical Education. Physicians should not be in the business of approving or disapproving schools that create the physicians' competitors, FTC argues.

May 1977. AMA lobbying barely averts adoption of a provision in Federal Trade Act amendments of 1977 that would have given FTC clear regulatory authority over deceptive advertising and fraudulent practices in nonprofit organizations, such as medical societies, with fines up to $5,000 per day. FTC says it has authority already, but it is not spelled out in the law and may be successfully challenged.

June 1977. FTC's Bureau of Competition sponsors two-day "Competition in Health Care" conference, laying theoretical groundwork for a free-market approach to medical profession and antitrust actions.

June 1977. Sen. Gaylord Nelson (D-Wis.) opens hearings on state licensing practices—including health professions—on the grounds that they foster "monopolistic" practices.

June 1977. Supreme Court rules in *Bates vs State Bar of Arizona* that bar associations cannot restrict lawyers' First Amendment right to advertise.

September 1977. FTC opens administrative "trial" of AMA and two Connecticut medical societies.

October 1977. Senator Kennedy, chairman of the health subcommittee and of antitrust and monopoly subcommittee, opens joint hearings on competition in health care industry.

Daniel C. Schwartz, 34, a 1969 George Washington University law school graduate, became the deputy director of FTC's Bureau of Competition just two months ago. Prior to that, he was the bureau's assistant director for evaluation for two years. He has been with FTC for four years and prior to that was an associate with the Washington law firm of Wilmer, Cutler & Pickering for four years. With bureau director Alfred F. Dougherty, Schwartz supervises FTC's staff of five lawyers working directly on the AMA suit.

Schwartz frankly concedes that FTC's original interest in applying antitrust principles to medicine—to which they have "historically not applied—arose because we saw the cost of health care growing so much." Surprisingly, then, he says that "in most industries, you would assume that with more competition, prices would go down, and there would be more options for consumers. We're not making that assumption in medicine. We're trying to determine whether that is in fact the case." What started as an attempt to force health costs down has become a test of the theory that medicine is subject to the law of supply and demand.

But whatever FTC discovers in this regard, the bureau's complaint will—if successful—accomplish one important objective, Schwartz says. "If we win the case, I will assume there will be an increased amount of information provided to the consumer about physicians. I'm not prepared to say what kind of information that will be." But it is bound to be helpful, he says, because current advertising restrictions on doctors "limit availability of information to consumers and their ability to get the services they need."

Schwartz says that he, too, is strongly against fraudulent and deceptive advertising. But he appears more confident than does Greenberg that such ads can and will be suppressed when medical societies can no longer discipline physicians. Who would do it? The Supreme Court's recent decision on lawyer advertising in *Bates vs State Bar of Arizona* (MWN, July 25, p. 10)—which destroyed most of the arguments raised by the bar for its regulation of attorney advertising—"does not indicate who has to do the regulating," says Schwartz. "All *Bates* says is that some form of regulation of deceptive advertising is permissible. . . . All our brief says is that the medical society can't regulate it. Our concern is that the regulation of advertising in this kind of situation be by a body or group or agency that does not have an inherent economic interest in the result."

Nevertheless, Schwartz concedes, "You're going to see more advertising—and more questionable advertising. One of the problems is, are you going to severely restrict advertising, regardless of social benefits, because some members of the profession will abuse that ability to advertise? I would hope that physicians think better of themselves than to think they will become used-car salesmen. I'm continually surprised by the concern of the AMA that the professional standards are so fragile that they will be endangered by the introduction of normal competition."

One of FTC's ongoing investigations, Schwartz says, clearly is looking at the question of the extent to which physicians compete with other health care personnel who could provide some of the same services, apparently adequately, at cheaper prices—for example, midwives.

"One of the concerns about dealing with chiropractors and other practitioners of so-called alternative health services is the question why the medical profession as such should be permitted to exclude competitive services from jurisdictions in which licensing agencies have permitted those alternative services." Physicians, Schwartz says, should not be forbidden by medical ethics to go into partnership with chiropractors any more than with clinical psychologists. "Of particular concern are restrictions on the ability of such physicians to gain access to hospital facilities, to gain insurance benefits, etc."

In the future, Schwartz says, FTC will be looking at access to the medical profession, restrictions on HMOs, the impact of fee-for-service insurance reimbursements on costs, and "a number of different areas as well. We are concerned, for example, about the possibility of conflict of interest or abuse of control by the medical professional who also controls the supply of other physician services, laboratory services, hardware, drugs—other kinds of products—and attempts to transfer what is to some extent a monopoly position to other parts of the marketplace: drugs, eyeglasses, orthopedic products, and so forth."

Kickbacks by laboratories will be another area of FTC's interest, even where they are not per se illegal. "From a competitor's standpoint, from an economic standpoint, there is not much difference between a physician who sends his patient to medical laboratory X and then receives back Y payment, and the physician who insists his patient use his own, in-office laboratory—and still gets Y payment," Schwartz says. "Whether the remedy would be to do away with all physician laboratories or not. . . . [He leaves the sentence unfinished.] There are some clear efficiencies and benefits in physicians' laboratories," he says.

The major problem with relative value scales, he says, is "who is going to do it. Who is going to set those values? Is it going to be the competitors, who are subject to them, or some other body?" Physician input is desirable, Schwartz says, but the actual charges should be "set by the marketplace." In this regard, he disagrees with the regulators at HEW, who are currently considering setting fixed fees for physician services (MWN, June 13, p. 49).

Ironically, Schwartz points out that FTC's authority for attempting to impose antitrust standards on the medical profession would not exist if its targets—the AMA and medical societies—were legally constituted labor unions. Unions are exempt from antitrust laws, he says.

continued

Bentyl™
(dicyclomine
hydrochloride)

Tablets, Capsules, Syrup, Injection
BRIEF SUMMARY

ACTION: Bentyl relieves smooth muscle spasm of the gastrointestinal tract.

INDICATIONS: For use as adjunctive therapy in the treatment of peptic ulcer. IT SHOULD BE NOTED AT THIS POINT IN TIME THAT THERE IS A LACK OF CONCURRENCE AS TO THE VALUE OF ANTICHOLINERGICS/ANTISPASMODICS IN THE TREATMENT OF GASTRIC ULCER. IT HAS NOT BEEN SHOWN CONCLUSIVELY WHETHER ANTICHOLINERGIC/ANTISPASMODIC DRUGS AID IN THE HEALING OF A PEPTIC ULCER, DECREASE THE RATE OF RECURRENCES, OR PREVENT COMPLICATION.

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as "probably" effective: May also be useful in the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis, acute enterocolitis, and functional gastrointestinal disorders) and in neurogenic bowel disturbances (including the splenic flexure syndrome and neurogenic colon). THESE FUNCTIONAL DISORDERS ARE OFTEN RELIEVED BY VARYING COMBINATIONS OF SEDATIVE, REASSURANCE, PHYSICIAN INTEREST, AND CORRECTION OF ENVIRONMENTAL FACTORS. For use in the treatment of infant colic (syrup). Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS: Obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy), obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis), paralytic ileus, intestinal atony of the elderly or debilitated patient, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis.

WARNINGS: In the presence of a high environmental temperature, heat prostration can occur with drug use (fever and heat stroke due to decreased sweating). Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful. Bentyl may produce drowsiness or blurred vision. In this event, the patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery or perform hazardous work while taking this drug.

PRECAUTIONS: Although studies have failed to demonstrate adverse effects of dicyclomine hydrochloride in glaucoma or in patients with prostatic hypertrophy, it should be prescribed with caution in patients known to have or suspected of having glaucoma or prostatic hypertrophy. Use with caution in patients with: Autonomic neuropathy. Hepatic or renal disease. Ulcerative colitis. Large doses may suppress intestinal motility to the point of producing a paralytic ileus and the use of this drug may precipitate or aggravate the serious complication of toxic megacolon. Hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, and hypertension. Hiatal hernia associated with reflux esophagitis since anticholinergic drugs may aggravate this condition. It should be noted that the use of anticholinergic/antispasmodic drugs in the treatment of gastric ulcer may produce a delay in gastric emptying time and may complicate such therapy (antral stasis). Do not rely on the use of the drug in the presence of complication of biliary tract disease. Investigate any tachycardia before giving anticholinergic (atropine-like) drugs since they may increase the heart rate. With overdosage, a curare-like action may occur.

ADVERSE REACTIONS: Anticholinergics/antispasmodics produce certain effects which may be physiologic or toxic depending upon the individual patient's response. The physician must delineate these. Adverse reactions may include xerostomia, urinary hesitancy and retention, blurred vision and tachycardia, palpitations, mydriasis, cycloplegia, increased ocular tension, loss of taste, headache, nervousness, drowsiness, weakness, dizziness, insomnia, nausea, vomiting, impotence, suppression of lactation, constipation, bloated feeling, severe allergic reaction or drug idiosyncrasies including anaphylaxis, urticaria and other dermal manifestations, some degree of mental confusion and/or excitement, especially in elderly persons, and decreased sweating.

DOSAGE AND ADMINISTRATION: Dosage must be adjusted to individual patient's needs.
Usual Dosage: Bentyl 10 mg. capsule and syrup
Adults: 1 or 2 capsules or teaspoonfuls syrup three or four times daily
Children: 1 capsule or teaspoonful syrup three or four times daily
Infants: ½ teaspoonful syrup three or four times daily. (May be diluted with equal volume of water.)
Bentyl 20 mg.: Adults: 1 tablet three or four times daily
Bentyl Injection: Adults: 20 mg. (2 ml.) every four to six hours intramuscularly only.
NOT FOR INTRAVENOUS USE.

Reference: 1. Lorber, S.H.: G.I. Dialogue #1. MERRELL-NATIONAL LABORATORIES, 1976

MERRELL-NATIONAL LABORATORIES
Division of Richardson-Merrell Inc.
Cincinnati, Ohio 45215

Merrell

6-40 (0000)

Beverlee Myers, who has a master's degree in public health from the University of Michigan, spent 11 years at HEW—from 1962 to 1973—working on Medicare, Medicaid, neighborhood health centers, and health planning before being put in charge of the "whole HMO effort under President Nixon." Surprisingly, then, she now heads Senator Kennedy's staff efforts in the antitrust field, perhaps proving that the senator from Massachusetts holds no grudges against his former foe's brightest talent, at least in the health field.

Myers also worked for three years—1973 to 1976—as the head of the New York State Medicaid program, until she quit abruptly, charging publicly that "the state didn't want me to run Medicaid." After a brief stint as a visiting lecturer at the University of Michigan School of Public Health, she joined the combined staffs of the Senate Human Resources Committee's health subcommittee and the Senate Judiciary Committee's antitrust and monopoly subcommittee (both chaired by Senator Kennedy) in May 1977.

In chairing two seemingly conflicting subcommittees, Senator Kennedy would appear to face an impossible task: defining public policy that satisfies both regulatory and free-market philosophies. In fact, however, Myers portrays Senator Kennedy's goal as essentially pragmatic: to break the grip of organized medicine on the health care industry.

continued

How doctors view attempts to foster competition

What are the feelings of physicians about the kind of future antitrust advocates are trying to fashion? Dr. John H. Budd, the Cleveland general practitioner who is this year's AMA president, says he is particularly bothered by the assertion that the practice of medicine is a business like any other. "If they're treated like businessmen, doctors will act like businessmen," Dr. Budd warns.

He is also less than impressed by FTC's argument that, once the medical profession is stripped of disciplinary power, the government will safeguard against fraudulent or misleading doctor advertising. "The government's track record is not that inspiring. If crime were turned over to the government [to do], even that wouldn't pay."

Neon signs on the lawn of a competing physician would not bother Dr. Budd personally, although he fears the effect of such gimmicks on the profession's public image. "I've been around a long time," he says. "My patients know me. I still think quality medical care is the best advertisement."

He says he is not against all forms of advertising, however, such as tasteful ads that give useful consumer information—office hours, specialty, and board certification. But he questions the purpose of advertising, say, which medical school the physician attended. "Someone might pick a doctor because he's a graduate of Harvard versus a graduate of Louisville," he observes. Such a choice would be "meaningless," however, because

continued

DOCTORS VIEW COMPETITION *continued*

both schools are equally competent to train good physicians, he says.

Similarly, a choice of surgeon on the basis of his mortality figures might also be counterproductive, Dr. Budd believes, because "the doctor with the high mortality figures might be the one who did the toughest operations." He does agree, however, that frequency of performing the same procedure is related to outcome and might be a valid criterion for a patient.

Dr. David W. Van Gelder of Baton Rouge, La., is this year's president of the American Academy of Pediatrics. He is primarily concerned with the effect of FTC and Justice Department actions on the quality of medical care. For example, allowing nurse-practitioners to work independent of physicians, he believes, might lead to overreferral or, worse, underreferral to physicians by nurses who think of themselves as less or more competent than they actually are.

And Dr. John C. Kelly, who takes over this month as president of the American Academy of Family Physicians, declares flatly that "the government wants mediocrity" as proved by its AMA suit. "There's more to medicine than dollars and cents. They tend to forget that. Most of the doctors I deal with like people—they don't give a damn if they make money or not."

Like Dr. Van Gelder, Dr. Kelly strongly believes nurse-practitioners must be under the supervision of a physician. If they were limited to the sort of triage decisions that medical corpsmen on the front lines had to make, setting up nurse-practitioners on their own might make sense, he says. "But they don't limit themselves to triage. They start out looking at sore throats and pretty soon they're treating myocardial infarctions. The problem is that their duties are not well defined."

Actually, some nursing schools turn out nurse-practitioners who might competently handle the more difficult cases, Dr. Kelly concedes, citing the program at the University of California at Davis. A kind of "Flexner report" for nursing schools might solve the dilemma, he says, but that would limit the "access" FTC officials hold so dear.

One thing Dr. Kelly says "wouldn't bother me at all" is public release of PSRO findings on physicians or of the results of disciplinary proceedings by hospital boards against one of their staff members. "If a doctor has problems and refuses to accept the help of his peers and the only way you can protect the public is to make disciplinary proceedings widely known, that's the way to go," he says.

Although "absolutely in favor of relicensure, based on the criteria of quality," Dr. Kelly hopes licensing boards would be allowed to take into consideration only objective criteria—such as test scores, perhaps even a social profile—but not individual complaints of dissatisfied patients, which are frequently subjective and based on misunderstanding. ■

TRUSTBUSTERS *continued*

Why? "The end is clearly how we can structure a health care system that will work more effectively in the public's interest and the consumer's interest. National health insurance. That's the ultimate end."

Myers leaves no doubt about which NHI plan Senator Kennedy has in mind. "I think we come out very clearly that the model of the Health Security Act is one that is not only viable but perhaps necessary as a mechanism to put some controlled discipline into the system," she says.

And what is wrong with the self-discipline of the medical profession—which FTC, HEW, and Senator Kennedy are trying to replace with either market forces or outside regulation? "We know the costs of the system are going through the ceiling at this point," she says, "and in part—in large part—because physicians have not exerted any self-discipline in the system."

What physicians have done, Myers contends, is exert control over who can practice and where—and under what conditions. The Kennedy health competition hearings were designed to find out the nature of this control and its effects on physician and nonphysician medical practice, on consumers, on industry, and on society.

"We know there is medical control—let's say in the medical profession—of licensure. How does this operate with respect to other kinds of professions? Is the medical profession also controlling the entry of new paraprofessionals? What is the role of the profession in terms of accreditation of medical schools?" Myers asks.

These are questions FTC also is exploring—but for the purpose of opening up medical care to vigorous competition, not to put control into the hands of government regulators. Senator Kennedy, like HEW, agrees with FTC on several points but seems to side with HEW where the two agencies disagree.

For example, Senator Kennedy is in favor of "promoting competition among delivery systems like HMOs," Myers says. He also believes in providing more information to the public. "One thing we wrote into the hospital cost-control bill was making available information to Health Systems Agencies on operations in the hospital. And the HSAs can publicize this information." But this would not apply to physicians, she adds. "I think we need to look into what information being collected by PSROs should be made more widely available."

But where HEW and FTC conflict in their views, such as whether there really *is* a free market in health care, Senator Kennedy sides with Secretary Califano's experts. "We come down on the fact that this is an industry that needs regulation," Myers says, "and that, from Senator Kennedy's point of view, the regulation should be more on the supply side than on the demand side. In other words, if we're aiming toward some comprehensive national health insurance program, then we need to regulate the supply side.

"Having come to that opinion, where—and how—should it be regulated? Who should be regulating? Our first cut at this is to explore the role of the medical profession in self-regulation and regulating the industry."

—REGINALD W. RHEIN JR.

American Medical
NEWS

MARCH 4, 1988

American Medical Association

INSIDE

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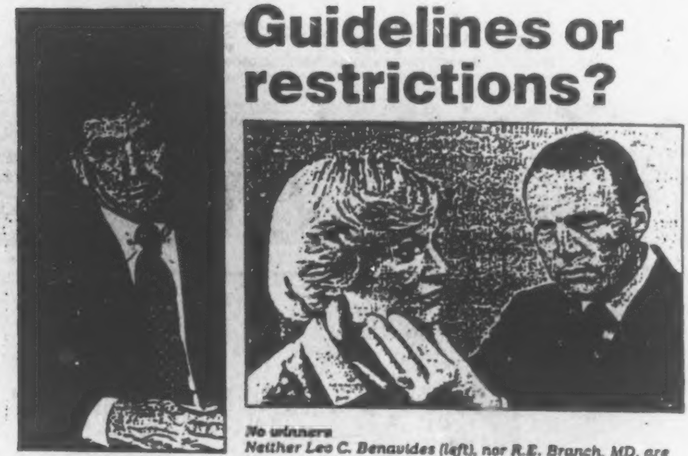
In the beginning there was an ad

Listings in the yellow pages escalated into a restraint of trade suit that involved a Texas MD (above), the county medical society, and the FTC. No one is happy with the results.

Guidelines or restrictions?



EARNEST J. BRYANT/AMA

No winners
Neither Leo C. Benavides (left), nor R.E. Branch, MD, are happy with the results of a dispute with the FTC.

Society, MD embroiled in FTC dispute

By Janice Perrone
AMN STAFF

Medical societies should be careful how they word their recommendations on members' advertising lest they be slapped with a restraint of trade order from the FTC — and Leo C. Benavides says his experience proves it.

Benavides is executive director of the Tarrant County (Texas) Medical Society, which for two years was embroiled in a restraint of trade controversy that grew out of a tiff about advertising recommendations. A consent agreement issued by the Federal Trade Commission in November settled charges against the society that it illegally restricted truthful advertising by its members, but both sides are still unhappy.

The FTC initially contacted the society in February, 1986, based on information supplied by R.E. Branch, MD, a board-certified otolaryngologic surgeon in Fort Worth, who felt that the society had been putting a lot of "heat" on him for advertising "out-of-field."

The FTC formally filed its complaint in August, 1987, charging that the 1,300-member, Fort Worth-based society, through its Board of Censors, restricted its members' advertising through limitations on the amount, duration, and size of newspaper ads.

The complaint charged that the society distributed restrictions to members that limited advertising in newspapers to 10 days and one-column inch in size and restricted or attempted to restrict the number of telephone directory listings its members placed and the size of the print.

UNDER the consent agreement, which the society agreed to when the complaint was filed last August, the society said it would not restrict such advertising in the future and published a copy of the complaint and order in its publication, *Physician.*

The society also agreed, for the next five years, to give each applicant for membership a copy of the order and, for the next 10 years, to provide written notice to any member whose advertising it intends to challenge and allow

See FTC, page 50

FTC involved in medical society/MD dispute over ads

Continued from page 3

that physician a reasonable opportunity to respond.

The agreement did not constitute admission of a law violation. But since it was formally issued in November, the agreement carries the force of law with respect to future actions. Violations of the order could result in a civil penalty of up to $10,000.

Today both sides still feel they acted within their rights and complain that they had to face serious accusations without knowing who their accuser was. The experience left Dr. Branch hurt and bitter; Benavides says the society is disappointed and frustrated.

These are their stories.

Yellow pages ads generate complaints

"I was called in the fall of 1985 by Dr. John Bremner, who at the time was the head of the [society's] Board of Censors," said Dr. Branch. "He said there'd been a number of complaints about my yellow pages advertising. It was a cordial conversation. He said maybe we could get together [and talk] before we start exchanging nasty letters. I said I'd like to do anything I could to comply."

Dr. Branch assumes the advertising in question was small, in-column ads under specific headings in the yellow pages, but he was never told what the specific complaints were or who the complainants were.

"I'm guessing it was the plastic and reconstructive surgeons," he said. "I was advertising to do liposuction. I had special training in liposuction, but the plastic and reconstructive surgeons were saying we weren't qualified to do that." He said he thinks that specialty's strategy is to monopolize the field, a charge they have rejected (*AMN*, Aug. 21, 1987).

"I'm surmising that it was [also] the allergists, pediatricians, and maybe the dermatologists who complained. I also ran in-column ads under those specialties because I have special training to do specific procedures in each of these areas [which I learned] through weekend seminars as part of my continuing medical education.

"I would defy anybody," said Dr. Branch, "to attend these meetings and find fault with [their] scientific efficacy or the quality of the presentations.

"There are little fiefdoms in medicine," he said. "I interface with allergy, plastic surgery, pediatrics. But my specialty has been cursed with a Latin name, and we have a real identity problem. In my opinion, if I didn't advertise under those specialties, the public wouldn't understand the ramifications of my medical and surgical specialties."

DR. BRANCH said he was familiar with FTC rules against restraint of trade. He had read a cease and desist act settlement printed in the *Journal of the American Medical Association* in 1982, after the AMA lost to the FTC a restraint of trade suit regarding medical advertising (*AMN*, Aug. 13, 1982).

"After Dr. Bremner phoned, I looked at my ads and I looked at the regulations, and I really couldn't see a problem," said Dr. Branch.

Dr. Branch then called the FTC to make sure the regulations hadn't changed. He was told they hadn't.

"When I went [to see Dr. Bremner] I brought copies of the cease and desist act in *JAMA* so he would know the rules. I doubt he ever read it.

"The county medical society president in 1985 should have looked at the regulations, but instead he apparently sent copies of my advertising to the State Board of Medical Examiners."

Letters from the State Board of Medical Examiners followed, and Dr. Branch began to fear he'd lose his license because of his advertising. "The implication from the executive director of the State Board of Medical Examiners, was 'be careful, or we'll come out and investigate you.'"

Dr. Branch then asked for a meeting with the entire Board of Censors, which took place in late 1985. That night the society was also holding an orientation for physicians new to the area. While he waited in the lobby, Dr. Branch noticed a copy of the society's advertising guidelines, which were routinely given to new physicians.

"Three years after the fact, they were still passing out guidelines that, in my opinion, were in flagrant violation of federal law," he said.

Dr. Branch met with the board and gave each member a copy of the *JAMA* article. "Again, I told them to point out where my advertising wasn't in compliance with the rules and I'd be happy to change it," he said.

TWO WEEKS later, Dr. Branch received a letter from the society. "It said, 'We find it unorthodox [that he was advertising under so many specialties] and we're concerned that you'd be liable for a lot of litigation.' I thought, 'Either they can't make heads or tails out of these regulations, or they didn't read them.'"

He contacted the FTC again.

"I never filed a complaint, but I did supply the FTC with information about what was happening to me," he said, "that [medical society board members] were leaning on me to stop advertising under certain specialties."

Also, "almost as an afterthought," he sent along a copy of the advertising guidelines he'd picked up the night he went to the Board of Censors meeting.

"Apparently, [the society] was then contacted by the FTC because they stopped pursuing their case against me. Although I didn't know until August of 1987, through a newspaper story, that the FTC was investigating them."

At the time the consent order was agreed to last August, an article appeared in the Forth Worth *Star-Telegram* noting the fact that the society felt the settlement would be detrimental to consumers. Dr. Branch contacted the paper to identify himself as the probable complainant and say that, in his opinion, the consent order benefited consumers.

"These regulations help physicians inform the public about the nature of their services," he said. "If you look at the yellow pages in Fort Worth now, they're filled with ads that make it easier for patients to find medical services."

The experience, however, did not turn out to be beneficial for Dr. Branch.

"I have gotten an extremely cold shoulder from the county society," he said. "My referrals have fallen off and it has affected my practice. I am not well regarded in this town because of this."

Did not mean to restrict trade — society

"We did not, in any way, mean to restrict trade," said Benavides.

Concerning the society's advertising guidelines, he said, "all we were doing was telling physicians new to the area that the usual and customary procedures in this community, which tends to be a conservative community, is an x by x ad for seven to 10 days. But we never said this was all you could do."

In terms of yellow pages advertising, Benavides said the society had recommendations about specialty listings so the public would not be misled.

"According to Texas law, physicians who are licensed may list themselves in any specialty, from neurosurgery to family practice," he said. "We were advising physicians to be careful because we have found that the public assumes a physician has special training if he or she is listed under a specialty.

"Our hope was that physicians would not list themselves unless they were board-eligible or board-certified or had some really significant training [in that area], not just CMEs. I look at CMEs as refresher courses.

"We felt it was our responsibility to the citizens of Tarrant County," continued Benavides, "to ensure that physicians were not being misleading.

"But we never said they couldn't list themselves however they wanted," he said. "We were never facetious enough to think that we could mandate how a doctor could advertise. [With Dr. Branch], we discussed the situation with him and advised him [against several specialty listings], and as far as we were concerned, that was it."

BENAVIDES says the consent order strips the society of the authority to ensure credentialing of physicians. "Basically, what the FTC has said is that you will not police yourself. Physicians can apparently list themselves in all the various specialties without any type of additional training in those specialties. The consumer is the one who loses here."

The consent order does allow the society to restrict deceptive and misleading advertising, but according to Benavides, the FTC has not provided a firm definition of 'deceptive and misleading.'

"If the speed limit is 55 and I'm doing 56, I know I'm speeding," said Benavides. "But here, they're not going to tell me what the speed limit is, but if I violate it, they're going to fine me $10,000. I'm not sure I'm willing to take that chance."

Since this controversy erupted, Benavides said the society "would never" challenge another physician's yellow pages advertising, and if a physician calls to ask about advertising guidelines, "we just tell them to do whatever they want. Now we no longer advise."

William David, the society's attorney, emphasized that there was never an admission of wrongdoing on the part of the county society, and that the FTC did not permit negotiation over the terms of the agreement. "They told us, 'Here is the copy. Either do what we say or we're going to take you to court.'"

THE SOCIETY is relatively small, he said, with limited resources, and couldn't afford a protracted suit with the FTC.

Both Benavides and David noted that during the controversy they had to defend themselves without knowing who their accuser was, since it's FTC policy not to reveal the identity of those making a complaint.

They also said they wouldn't be surprised if other county medical societies run into the same trouble.

"If the physician doing the orientation for new physicians is reading from a script and fails to say, 'We recommend,' and just says, 'Do this,' they could have a lot of problems," Benavides said. "The semantics of the wording could easily be considered restraint of trade. We happened to have someone who was sensitive to this who contacted the FTC."

It could happen again, David warns. "The first time another society gets a complaint, it's going to end up the same way."

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 102
(A-89)

Introduced by: Louis F. Alfano, M. D., Delegate
American Society of Abdominal Surgeons

Subject: Need for Standards for Truthful Medical Advertising

Referred to: Reference Committee on Amendments to Constitution
and Bylaws (Richard B. Tompkins, M. D., Chairman)

Whereas, The Federal Trade Commission has effectively barred the American Medical Association from establishing meaningful standards for medical advertising that is truthful, informative and not deceptive; and

Whereas, State and county medical societies are similarly barred from establishing or enforcing such standards with respect to their members; and

Whereas, State medical licensure authorities are similarly restricted; and

Whereas, The American public has been endangered by deceptive, untruthful medical advertising promising risk-free, pain-free out-patient treatment and surgery without loss of time from work, and results far beyond reasonable expectations; and

Whereas, Much of this treatment and surgery, particularly elective cosmetic procedures, is performed by physicians without specialized training in the procedures they perform and with inadequate facilities; and

Whereas, The Federal Trade Commission, while effectively barring private organizations from establishing and enforcing standards, does not exercise its authority to adopt and enforce reasonable standards for medical advertising; therefore be it

RESOLVED, That the American Medical Association request the Federal Trade Commission to conduct hearings, where interested parties may be heard, for the purpose of establishing Federal Trade Commission standards governing truthful, non-deceptive and non-misleading advertising.

Fiscal Note: $2,000

medical economics
FOR SURGEONS

COMPETITION AMONG SURGEONS TAKES A TOUGH NEW TURN

Surgeons have started suing surgeons over who should be allowed into their ORs, and it looks like the turf battles are spreading.

By Mark Crane SENIOR ASSOCIATE EDITOR

Who's the doctor of choice for treating a herniated disc—an orthopedist or a neurosurgeon? Should a candidate for rhinoplasty see a plastic surgeon or an otolaryngologist? Is an OBG specialist more adept than a general surgeon in performing a hysterectomy?

Such questions have long inspired fiery debate in doctors' lounges and at staff meetings. But, now, with the explosion of the physician population and with fierce competition for patients and hospital privileges, these disputes often lead to court fights, and sometimes to federal investigations. Consider these examples:

▶ A Phoenix general surgeon recently won a $60,000 defamation suit against an ENT specialist he says made false accusations about him before a hospital surgical committee and the state medical board. The general surgeon claims his accuser acted out of fear of losing patients to him.

▶ In Atlanta, otolaryngologists have filed a $10 million suit against two plastic surgeons and the Georgia Society of Plastic Surgeons for statements that, the plaintiffs claim, disparage their qualifications.

▶ On the national level, a long-standing feud between plastic surgeons and otolaryngologists who perform facial cosmetic operations has prompted: media blitzes by both specialties, a Federal Trade Commission probe, and a truce mission by the American College of Surgeons.

▶ An ENT specialist in Kansas City, Mo., who limits his practice to facial plastic surgery, holds privileges for such procedures at five local hospitals. But he's been denied privileges at a sixth because that hospital says otolaryngologists aren't qualified for most facial cosmetic surgery. He counters that the plastic surgeons on that staff simply want it all for themselves.

While some of the latest skirmishes undoubtedly involve personality conflicts, the intensity with which they're being waged could be a harbinger for more surgical specialties. As training programs are adapted to reflect changes in real-world medicine, you may see incursions into your own field escalate from the nuisance category to a full-scale invasion.

Peer review or peer containment?

Five years ago in Phoenix, general surgeon Merrill S. Chernov lost his privileges to perform head and neck operations without supervision at Doctors Hospital, a Humana-owned facility. Six months' worth of his charts were scrutinized by the hospital's surgical committee and the Arizona State Board of Medical Examiners. Chernov charged that another surgeon on the staff, otolaryngologist Monte C. Nowak, manipulated the peer review process to eliminate Chernov as a competitor.

The conflict began when Chernov removed a benign mass from the neck of a middle-aged bank

OPERATING ROOM

AUGUST 19

employee, Violette G. Maggio, in November 1978. Nowak testified before the surgical committee—of which he's a member—that he'd examined Mrs. Maggio at Chernov's request before her operation and had told the surgeon that the mass was a parotid tumor. According to Nowak, Chernov failed to remove the parotid gland when he took out the mass, so the surgery fell below established standards.

Chernov protested that he'd asked Nowak to examine the patient in the OR, but that Nowak had refused—a contention bolstered during the defamation trial by testimony from two other attending physicians and the patient herself.

Nowak insisted that whatever comments he made in committee were privileged because of state laws regulating peer review in hospitals. But Chernov's attorneys argued that such privilege is waived when there's evidence of bad faith or malice. The motive Chernov presented for establishing malice: Nowak's fear of losing otolaryngology cases to him.

Shortly before the trial, Chernov offered to settle the suit for $1 and a letter of apology. "There'd been a lot of mental stress, time, and money involved. The medical community was forced to choose sides—all over a satisfied patient with an excellent result," he says. "I just wanted it on the record that I wasn't in error. But Nowak refused my offer."

In April 1982, a jury awarded Chernov $40,000 in compensatory damages and $10,000 in punitive damages, which the hospital paid on Nowak's behalf. The state medical board, meanwhile, had decided to take no action against Chernov. Though he still operates at Doctors Hospital, it has hardly been a complete victory for him. His head and neck privileges remain suspended, with the surgeon unable to persuade the surgical committee that he's fully qualified for such procedures.

The battle for facial cases

Other disputes have implications for entire specialties. Across the country in Georgia, otolaryngologists are the plaintiffs in a defamation suit that's illustrative of their decade-long struggle with plastic surgeons. What's at stake is awesome, considering the 500,000-plus facial cosmetic procedures performed nationwide each year.

The suit was precipitated by two articles in the Journal of the Medical Association of Georgia. In October 1981, two otolaryngologists described how their traditional ENT designation had changed to "head and neck medicine and surgery" to reflect a "quiet evolution" in training in recent years. The article cited the field's history in plastic and maxillofacial surgery, stressing otolaryngologist Sir Harold Gillies' role as the father of modern plastic surgery.

Four months later, there was a barbed reply by two former presidents of the Georgia Society of Plastic Surgeons. They responded in the same journal with a broadside entitled, "Things Are Never What They Seem, Skim Milk Masquerades as Cream." That line, from Gilbert & Sullivan's "H.M.S. Pinafore," left no doubt the authors considered their specialty the cream of the crop, and otolaryngologists mere pretenders.

That second article attacked two otolaryngology organizations—the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS) and the American Association of Cosmetic Surgeons—as "splinter groups . . . blissfully devoid of formal qualifications." The authors contended that otolaryngologists "invade" aesthetic surgery because the advent of antibiotics has allowed numerous ear, nose, and throat diseases to be successfully treated without operations.

After their request for a retraction was rebuffed, the otolaryngologists responded with the lawsuit. E. Gaylon McCollough, a Birmingham, Ala., otolaryngologist and secretary of AAFPRS, characterizes the plastic surgeons' assault as part of a concerted campaign to disparage his field.

"This article contains the same title and reproachful phrases—word for word—as a 1975 article published in the Pima County [Ariz.] Medical Society's magazine by another plastic surgeon," he says. "If there isn't an organized campaign to discredit us, then it's pretty strange how these plastic surgeons happened to make identical remarks six years and 2,000 miles apart."

The otolaryngologists drew some ammunition for

"They [illegible] that facial plastic surgery isn't part of otolaryngology."

their suit from a lengthy (although inconclusive) investigation two years ago by the Federal Trade Commission of possible antitrust violations by the American Society of Plastic and Reconstructive Surgeons (ASPRS). That probe gave otolaryngologists access to ASPRS documents that had become part of the public record. One was a 1975 memo written by Dallas F. Whaley, ASPRS' executive director, entitled "Intergroup Conflict."

The memo outlines a strategy to "stall and frustrate" efforts by otolaryngologists to achieve recognition from organized medicine while "making it appear that ASPRS is working with them to improve their educational background in cosmetic surgery."

McCollough says of the memo: "It's an example of how insecure plastic surgeons have become. We'd hoped their campaign to eliminate competition would run out of steam. But the 'Skim Milk' article, plus magazine ads saying that only board-certified plastic surgeons are qualified to perform cosmetic surgery and scores of local battles where they've tried to deny hospital privileges to otolaryngologists, prove that 'intergroup conflict' lives on—despite what the ASPRS leadership says."

The war for hospital privileges

Turf battles may directly affect individual surgeons' practices as more hospitals close departments to new staff appointments and tighten up their ER rotations. In such cases, it's often hard to tell where the blame lies—with the doctor surplus or with established surgeons trying to limit competition.

Take the case of the Kansas City, Mo., surgeon Edwin A. Cortez, who joined a group of ENT specialists there two years ago. He limits his practice to facial plastic and reconstructive surgery.

"My application for such privileges at Saint Joseph Hospital wasn't acted upon for a year, and when I was finally granted privileges, no plastic surgery was allowed," says Cortez. "I was told the hospital didn't have a category for someone with my background—a board-certified otolaryngologist with a fellowship in facial plastic surgery from the AAFPRS. Yet I had no trouble getting these privileges at five other Kansas City hospitals."

After Cortez protested, the medical staff at Saint Joseph appointed a multispecialty ad hoc committee to review his credentials. The committee unanimously recommended that Cortez receive privileges for facial plastic procedures, but the executive board still denied them.

"They said, in effect, that facial plastic surgery isn't part of otolaryngology," Cortez argues. "They stopped me from doing what I specialise in and what my boards and training give me the right to do. It wasn't because of peer review of any operation, but simply because of what I am."

There's no turning the other cheek

For their part, leaders of ASPRS, the largest plastic surgery organisation, deny that there's a campaign against doctors in any surgical field. Its president, San Francisco plastic surgeon Mark Gorney, bristles at the mention. "There are small groups of individuals on both sides—in plastic surgery and otolaryngology—who continuously stir up this deplorable internecine conflict that can only harm both specialties," he says.

Organised plastic surgery has never tried to stop otolaryngologists from doing cosmetic work, Gorney contends. "Without doubt, there are individuals who act as self-appointed champions of our specialty and ASPRS deplores this, but it's legally impossible for us to restrain our members. We recognise legitimate overlap by different specialties but hospital privileges are a local matter and we take no position," he says.

The "intergroup conflict" memo uncovered by the FTC is a sore point with Gorney, who calls it a red herring. "That memo was written by a lay employee with no policy-making authority," Gorney says. "He prepared it on his own and gave it to then-ASPRS president Ross Musgrave, who filed it. The memo was never implemented in any way. Yet the facial surgeons' academy has gleefully unearthed it like some dinosaur bone and laid it at our doorstep as proof that we're out to get them."

Gorney also points out that otolaryngologists don't

[redacted]

hesitate to belittle the credentials of ASPRS members. A recent society poll shows that the great majority of operations performed by most plastic surgeons are reconstructive in nature, and just under one-third involve facial aesthetics. Nonetheless, the March 1982 Facial Plastic Times—an otolaryngology publication—comments that "many general plastic surgeons have difficulty mastering the complex anatomy of the head and neck" because of their lack of training and the infrequency with which they operate on the face. "So who's disparaging whom?" Gorney asks.

Some ASPRS members are enraged by the terminology that's developed in the feud. "The otolaryngologists' full-page ads in Vogue and Glamour magazines suggest that patients considering cosmetic operations see only a 'specialty plastic surgeon'—meaning one of their members," Gorney says. "It implies they are the superspecialists of the face and we're only generalists. We resent this attempt to make plastic surgery a generic term. What is a 'specialty' plastic surgeon anyway? Is a podiatrist a 'specialty' orthopedist?"

The hostilities aren't likely to end soon, and numbers are the main reason. One study predicts that by the year 2000 the ratio of plastic surgeons to general population will be eight times greater than it is today. Add to that more otolaryngologists entering cosmetic surgery, and you have an increasingly volatile combination.

While the feud between plastic surgeons and ENT specialists is the most ferocious in medicine, there's also considerable friction between orthopedists and neurosurgeons over spinal surgery, between general surgeons and OBG specialists over hysterectomies, orthopedists and plastic surgeons over hand procedures, and neurosurgeons and radiologists over invasive blood-vessel imaging.

Turf battles have a severe effect on pediatric surgery, which overlaps several fields. "Some hospitals won't allow a pediatric surgeon to open a baby's chest because he doesn't have a thoracic board certificate—or he can't take out a cancer of the kidney because he doesn't have a urology board," says Anthony Shaw, a pediatric surgeon in Duarte, Calif. "There's now a two-year requirement beyond the five years of training in general surgery to be certified in pediatric surgery. If a pediatric surgeon also has to secure board certificates in thoracic surgery, urology, and other specialties, he could be 45 years old before he's done."

However, such feuding has prompted at least two formerly antagonistic groups to attempt to reduce friction. Since Jan. 1, almost 7,000 neurosurgeons and orthopedists have attended courses jointly sponsored by their specialty societies on the use of chymopapain for intradiscal therapy. Considering previous relations between the American Academy of Orthopaedic Surgeons (AAOS) and the American Association of Neurological Surgeons (AANS), it was a bit like the Yankees and the Red Sox getting together to exchange scouting reports.

"We anticipated the FDA's release of chymopapain and realized it would be used by both orthopedists and neurosurgeons," says David G. Murray, a Syracuse, N.Y., orthopedist and AAOS past president. Neither group wanted to see inadequately trained professionals bring discredit to the new technique and bring harm to patients.

Still, the potential for new conflict due to the doctor surplus worries surgeons in other fields. One of them is plastic surgeon Gorney. "Patient visits will drop for all doctors. Quarreling will become more vulgar, and there could be a serious deterioration of ethics," he says.

Murray is less pessimistic. He expects few conflicts between orthopedists and other surgeons. "But," he warns, "some orthopedists will have to move away from saturated areas into regions that are underserved. Others will go into the military and teaching, where there's a shortage of orthopedists, and others will go into government and disability-evaluation work."

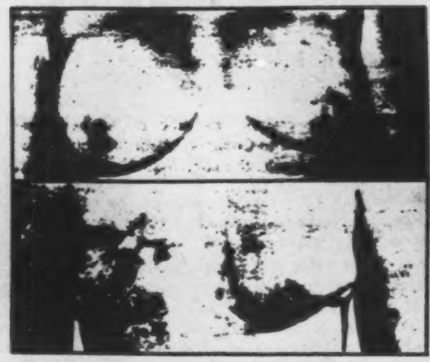
Frank R. Wrenn, a Greenville, S.C., neurosurgeon and past president of the American Association of Neurological Surgeons, says all doctors will have a tougher time drawing the line between professional self-regulation and professional self-interest. "And the more public these fights become, the greater the likelihood of government intervention." ■

ARE WE RESTRAINING COMPETITION OR HUMAN MISERY?

The Federal Trade Commission is contemplating a complaint against the American Society of Plastic and Reconstructive Surgeons for controls it seeks to maintain for the specialty

MARK GORNEY, M.D., F.A.C.S.

IN SOUTHERN CALIFORNIA, a 41-year-old woman reads an advertisement for cosmetic breast surgery. She considers her breasts too full and doesn't like their slight sag so she responds to the ad. The doctor is an unscrupulous, untrained individual with a long record of shady activities. He reassures the woman that the breast operation she seeks is a simple procedure. As a result of the surgery, she is grossly deformed (as shown in the accompanying photographs).



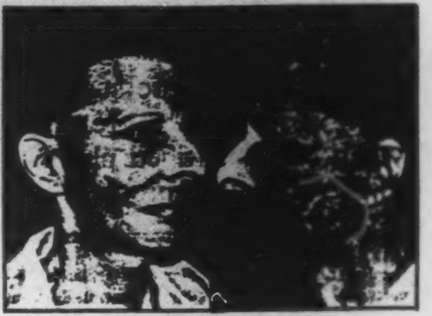
How could such a catastrophe have been produced by "cosmetic" surgery? As a plastic surgeon, I say that the man who performed the procedure showed an utter lack of training or judgment—or both.

Another woman met her death after responding to an ad by a self-styled "plastic surgeon." His impressive curriculm vitae included membership in nonexistent organizations. He was willing to do the "tummy tuck" operation the woman wanted. She weighed over 200 pounds and was a brittle diabetic and a heroin addict and had been advised by a number of ethical plastic surgeons not to have the operation. The man who snared her with his ad proceeded without adequate preoperative laboratory work. The woman died of wholly predictable, massive complications.

After a 'tummy tuck,' a brittle diabetic who weighed over 200 pounds died of predictable complications

Stimulated by a glowing advertisement showing a radiantly smiling patient telling how much her "new" nose had improved her life, a young man in Los Angeles sought a rhinoplasty. The surgeon, who fraudulently billed himself as a "board certified cosmetic surgeon" (a nonexistent board), performed *four* operations. Each result was worse than the previous one and finally the young man lost most of his nose. He became a psychiatric cripple, a recluse, and required 10 operations (at a cost of over $50,000) to reconstruct his nose into some semblance of normality.

Another patient saw a display ad in the Las Vegas Yellow Pages and decided to have facial aesthetic surgery to improve her appearance. The operation led to gross disfigurement, as shown in the accompanying photos. The advertising physician, an osteopath, was not board certified in plastic surgery and has since been disciplined by the Nevada State Board of Osteopathy. His license was suspended after the board questioned his competency in surgery and found him guilty of unprofessional conduct in placing misleading advertising.



An ad for a facelift spelled disaster for another woman. She had already consulted two bona fide plastic surgeons about such an operation when she was attracted by the ad in her local newspaper. She did attempt to check the physician's qualifications with the local medical society. Told that the society had "nothing negative" on him, she interpreted this to be an endorsement. Actually, he was an internist-cardiologist without any formal training in surgery. He had taken a 20-hour course in "facial plastic surgery" and then set himself up in business.

But the woman had no way of knowing this when she submitted to the operation. After seven hours of surgery, she realized that something was seriously wrong. She insisted that the physician call an ambulance. She was in great pain and bleeding profusely and her face was severely swollen. At the hospital, a blood dyscrasia workup was done. Not until a week later did a board certified plastic surgeon diagnose

Address reprint requests to Mark Gorney, M.D., F.A.C.S., Plastic Surgery Medical Group, 909 Hyde St., Suite 620, San Francisco, Cal. 94109 unevacuated bilateral hematomas. By this time she also had a partial slough of her "facelift" flap and a partial facial palsy. At best, this patient will have irreversible facial damage and psychological scars. She is now under psychiatric care for suicidal tendencies.

The common denominator in all these tragic cases is advertising by unscrupulous persons who are not qualified to attempt the procedures they promise. The physicians involved displayed abominable lack of judgment: They performed the wrong operation on the wrong patient for the wrong reason under the wrong circumstances.

Is it any wonder that the American Society of Plastic and Reconstructive Surgeons thinks that advertising is less than ethical? Is it any wonder that the society believes that individuals holding themselves out to do plastic surgery should be certified by the American Board of Plastic Surgery?

Advertised cosmetic surgery cost 25% to 200% more than when board-certified plastic surgeons did the procedures

The Federal Trade Commission (FTC) takes a different view. In a contemplated complaint, its Bureau of Competition charged the society with interfering with the rights of physicians not certified by the American Board of Plastic Surgery to perform plastic surgery procedures. To open up competition, the FTC seems bent on lowering standards. Theoretically, such lowering of quality of care should bring down the cost of care.

One of the most important elements in the FTC effort is to do away with restrictive codes of ethics and encourage advertising and solicitation of patients. Ironically, an informal study conducted in Southern California showed that advertisers charge anywhere from 25% to 200% higher than the median for the same procedure by a board certified plastic surgeon. It stands to reason that when you are spending $250,000 to $300,000 a year on advertising, the money has to come from patients' pockets. To justify such expenditures, you have to do a "volume" business. I can think of no surer road to disaster than to operate on everyone who applies for plastic surgery, disregarding any criteria other than the ability to pay.

For more than a year, the American Society of Plastic and Reconstructive Surgeons, through legal counsel, has let the FTC know that its contemplated complaint is not in the best interests of the American consumer. As a result, the FTC has made some modifications in the proposed complaint, but the document continues to be unacceptable, and our officers will not sign a consent order.

MARK GORNEY, M.D., F.A.C.S., is a board-certified plastic surgeon practicing in San Francisco. He was chief of plastic surgery at St. Luke's Hospital there from 1971 to 1978. A member of the Board of Directors of the American Society of Plastic and Reconstructive Surgeons, he chairs its Patient Protection Commission. He was president of the California Society of Plastic Surgeons from 1978 to 1979 and is an examiner for the American Board of Plastic Surgery.

In the past several months, other groups have risen up and complained to Congress about the activities of the FTC. As a result, the commission seems to have slowed down somewhat. But its staffers haven't dropped their efforts. For us plastic surgeons, this has created an unacceptable state of limbo. We're on the FTC's hook, and it won't let us off.

We think we're on that hook because of a profound misunderstanding. What we see as our duty to protect the patient against rip-off artists and charlatans, the FTC interprets as an infringement of First Amendment rights. (Advertising is considered "commercial free speech.") What we believe is our obligation to maintain the highest possible standards of quality, the FTC views as illegal restraint of trade.

Ours is the smallest recognized specialty, numbering about 2,000 board-certified individuals. The segment of surgical care we provide is mostly elective and not affected by federal reimbursement. Why then has our organization been chosen as a target for the FTC?

Perhaps the answer lies in what seems to be a pervasive philosophy at the commission. Two years ago, an assistant director of the FTC's Bureau of Competition, Jonathan E. Gaines, made a speech to the American Society of Association Executives/Professional Associations Council in Washington, D.C. In it, he said: "If you want to think a little more deeply about the restraint, consider which particular procedures are likely to be performed; whether they are more likely to be performed after instruction than absent instruction; whether the instruction given is clearly inadequate, and whether some actual harm is probable if those who received the instruction were to offer services based on what they learned. Then ask yourself again, is the restraint really necessary to protect the public?"

A little more of the philosophy at the FTC emerged in another speech by Gaines a couple of weeks after that just quoted. At a symposium on trade association law and practice sponsored by the Antitrust Law Committee of the Bar Association of the District of Columbia, he said: "Quality is everyone's objective, but do not forget that not all consumers can afford the highest quality."

No one can quarrel with the objective of lowering the cost of medical care. But at what expense will this reduction come? The small stream of disastrous complications is growing larger. Deaths are beginning to be reported from these elective procedures. If the FTC prevails in its philosophy, this stream could become a torrent.

Officials at the FTC have accused us of distorting their position and unfairly accusing them of being at least partly responsible for the increasing number of surgical disasters. Unfortunately, our area of specialization seems to attract persons who would rather prey on unsuspecting patients than earn proper credentials to perform the procedures they promise. We have always had charlatans and probably always will. That's why the medical profession for 75 years has fought to eliminate quackery and hucksterism. That's why we seek to control the practice of our specialty at the state and local level.

Since the FTC promulgated its policy of attacking restraints within the medical profession several years ago, we have noticed a virtual explosion in the number of unqualified individuals who are openly advertising for patients. What was once a problem localized in Southern California is now spreading like a metastasizing cancer across the country. It has become evident in Nevada, Georgia, Florida, and New York. Have the FTC's policies directly aided and abetted these unscrupulous individuals? Perhaps the best answer can be found in their advertising copy and the defenses they raise when state authorities intervene. In every instance of which I am aware, lawyers for these persons have issued statements to the effect that they felt encouraged to carry on their activities by the FTC.

A few years ago, an FTC economist, Warren Greenberg, was asked whether the FTC's rulings might not have a deleterious effect on patient care. According to *Medical World News* (October 17, 1977, page 51), he answered: "I won't deny the fact that some people will go into brain surgery and have consequences that we all don't want. There will be costs—really serious costs—but the benefits are that we will know what the hell's going on in the medical marketplace."

We have another concern. The lurid headlines created by every catastrophe always point to "plastic surgeons" without making any distinction between those who are and are not qualified by board certification. What effect will this have on our insurability? Will our rates skyrocket or will coverage become unavailable? That is another "medical marketplace" consideration that should be given some thought.

But is the thinking at FTC clear? Last August, Alan Palmer, deputy director of the Bureau of Competition answered questions at the annual meeting of the Organization of State Medical Association Presidents. One of the questions: "How about the relative value schedules ordered by one government agency—the U.S. Department of Health, Education, and Welfare—as a requirement for participation in Medicare and CHAMPUS, and the conflicting action of the FTC in suing the medical organizations because such schedules are, in its opinion, a restraint of trade? Palmer's reply: "I can see where you would have a problem." Palmer is now on leave of absence from the FTC spending a year at Yale.

Where will it all end? The FTC, with its inexhaustible resources and personnel, is obviously in a much stronger position than a small organization of physicians. But is it fair for a group of lawyers, without any consultation from the concerned physicians, to promulgate policies on the delivery of health care services—based on some Supreme Court decision on fee setting by lawyers?

The FTC appears determined to counteract organized medicine's efforts to eliminate charlatanism, maintain the quality of medical education, and establish competent standards to protect the public. This course could seriously jeopardize the quality of medical care in the United States—without any perceptible effect on the cost of health care. The American Society of Plastic and Reconstructive Surgeons is determined to fight this tragically misdirected attack on behalf of all specialties.

Lurid headlines never distinguish between a board-certified plastic surgeon and one who is not

There is some hope. Justice Potter Stewart has eloquently summarized our concerns. In the Supreme Court decision on the *Virginia Pharmacy* case, he said: "The legislature was not dealing with traders in commodities, but with the vital interest of public health, and with a profession treating bodily ills and demanding different standards of conduct from those which are traditional in the competition of the market place. The community is concerned with the maintenance of professional standards which will insure not only competency in individual practitioners, but protection against those who would prey upon a public peculiarly susceptible to imposition through alluring promises of physical relief. . . . The community is concerned in providing safeguards not only against deception, but against practices which would tend to demoralize the profession by forcing its members into an unseemly rivalry which would enlarge the opportunities of the least scrupulous." ■

Would YOU Advertise?

LAMP survey shows a shift in attitude among physicians on ethical restrictions

LAMP Staff

DON'T EXPECT a stampede of physicians on Madison Avenue, but a growing number of doctors would like to see the ethical restrictions that have prevented them from advertising eliminated.

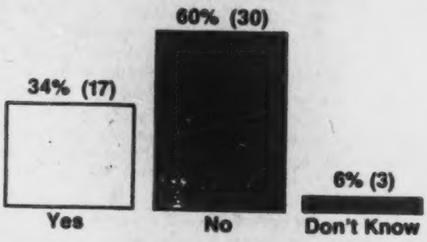
A random survey of 50 general and family practitioners shows that more physicians oppose the ethical guidelines of the American Medical Association that have discouraged them from advertising than a year ago. Of 50 physicians interviewed, 17—or 34%—answered "yes" when asked: "Do you feel ethical restrictions that prevent physicians from soliciting patients through advertising should be eliminated?"

One year ago, a similar poll taken by LEGAL ASPECTS OF MEDICAL PRACTICE showed that 26% favored the elimination of such restrictions. However, when physicians were asked whether they would advertise their services if certain restrictions were dropped, only seven, or 14%, replied that they would do so. That figure is identical with the number who said they would advertise when the survey was conducted a year ago.

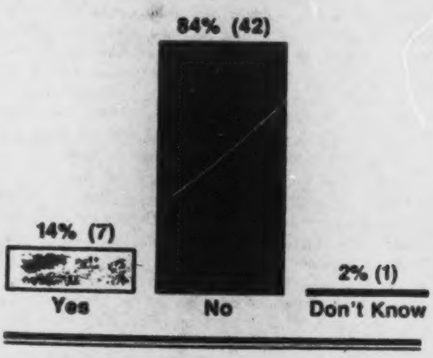
A new question was added to the survey this year. When physicians were asked if their attitudes today are any more favorable toward advertising than they were five years ago, 13, or 26%, replied "yes." Among those who replied that their attitudes were not any more favorable than before are some who favored advertising previously but reported no change in how they felt.

The names of the 50 physicians were randomly chosen from the AMA directory of all physicians in the United States.■

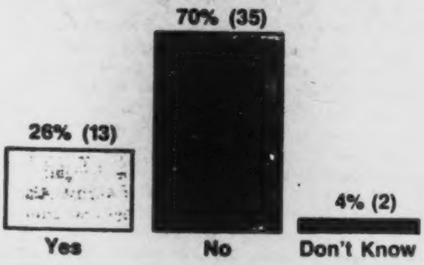
Do you feel ethical restrictions that prevent physicians from soliciting patients through advertising should be eliminated?



If restrictions that prohibit certain kinds of advertising by physicians were eliminated, would you want to advertise your services?



Is your attitude today toward advertising by physicians any more favorable than it was, say, five years ago?



Address reprint requests to Hilda Regier, Managing Editor, Legal Aspects of Medical Practice, *747 Third Ave., New York, N.Y. 10017*

The Washington Post

A WEEKLY JOURNAL OF MEDICINE,

HEALTH

SCIENCE AND SOCIETY

ROE v. WADE

FAT SUCTIONING

SURGEONS BATTLE OVER WHO SHOULD DO THE MOST POPULAR COSMETIC OPERATION IN AMERICA

By Robin Marantz Henig
Special to The Washington Post

In quest of the Holy Grail of the fitness-conscious 1980s—a youthful, lean, hard body—many people seem to have found a shortcut. Instead of sweating through exercises or struggling with diets, hundreds of thousands are choosing to have their fat sucked away.

This fat-removal operation, called liposuction, was imported from France in 1982 and is already the most popular cosmetic operation in America.

But don't let the quick-fix appeal fool you. liposuction can be risky business. Potential hazards range from the minor—skin dimpling, discoloration, numbness, lumpiness—to the life-threatening—infection, blood clot, or a piece of fat that can get into the bloodstream and lodge in the lungs or the brain.

Don't be fooled, either, by the smooth talk of cosmetic surgeons in their Yellow Pages ads. Liposuction, one of the few growth industries in the medical marketplace, is the subject of a battle for a piece of the medical practice pie. That struggle has grown bitter, and only—for patients caught in the crossfire—sometimes downright dangerous.

At least 11 liposuction deaths have been reported, some at the hands of physicians whose liposuction training was limited to one three-day workshop—and who were perfectly truthful when they called themselves certified lipoemtologists.

This morning, Rep. Ron Wyden (D-Ore.), chairman of the House Small Business subcommittee on regulation and business opportunities, opens hearings on cosmetic surgery, including liposuction. He plans to examine such issues as who should perform these operations and how practitioners should be accredited and regulated.

"When . . . regulatory breakdown leaves victims physically and emotionally scarred and financially drained, the American people have every reason to know why," Wyden says.

What is confusing to many clients are the different claims made by surgeons on who can and who cannot perform a liposuction.

"At present, I don't think anyone can guarantee that you're getting a person qualified to perform a given procedure," even with board certification in a particular surgical specialty, says Richard Webster, a retired plastic surgeon who has taught both cosmetic surgery and otolaryngology at Harvard and Boston University medical schools. "Peer review and board certifying mechanisms should deal with specific procedures."

For the estimated 250,000 patients, almost all of them women, who will choose liposuction this year, one important question—after the obvious "Why?"—is "Who?" What kind of doctor should perform the procedure?

To answer this question, a woman first must understand the struggle between two powerful organized medical groups.

What is confusing to many clients are the different claims made by surgeons on who can and who cannot perform a liposuction.

Plastic surgeons, who are trained in plastic and reconstructive surgery, are competing with cosmetic surgeons, who are certified in a range of specialties from gynecology to dermatology with some additional training in cosmetic procedures. At stake is control of the deep pocket of American vanity.

"My own discipline says they are the only ones qualified to do liposuction," says plastic surgeon Webster. "Obviously, this isn't so. A large number of men in other fields started doing liposuction at least as early as plastic surgeons did, or even earlier."

The conflict over who should do liposuction came to a head in 1987, when a Houston gynecologist-turned-liposuctionist was accused of killing two patients who developed infections after being suctioned in his office. The gynecologist, whose medical license was revoked and whose whereabouts are unknown, had attended a weekend course in liposuction sponsored by the American Society of Liposuction Surgery.

"It shouldn't be [plastic surgeons'] prerogative to bad-mouth other specialties," John Newman, one of the founders of the society, told American Medical News at the time. "They took the [Houston] case and blew it out of proportion."

After those two deaths, the plastic surgeons' organization, the American Society of Plastic and Reconstructive Surgery, issued a report documenting 11 deaths from liposuction since 1982. "Unless organized medicine increases its peer review efforts and devises guidelines governing who is permitted to perform and advertise surgical procedures," the report warns, "further complications and overuse of suction lipectomy are foreseen."

It seemed the gauntlet was being thrown down.

But the plastic surgeons insist they are not bickering, only educating.

"This is not a turf battle," says Simon Fredricks, a plastic surgeon at the Baylor College of Medicine and author of the Society report. "This is an attempt to enunciate our concern about the welfare of the American people," which is being threatened by "those who are attempting to ply their craft without experience or legitimate and proper training."

Turf battle or not, the various specialists who perform liposuction have certainly been doing a lot of staking out of territory. They include:

- The American Society of Plastic and Reconstructive Surgery, the granddaddy of plastic surgery organizations. The word "plastic" comes from the Greek "plastikos," meaning "to mold." Plastic surgeons, who number about 3,000 in this country, perform both cosmetic surgery to enhance normal

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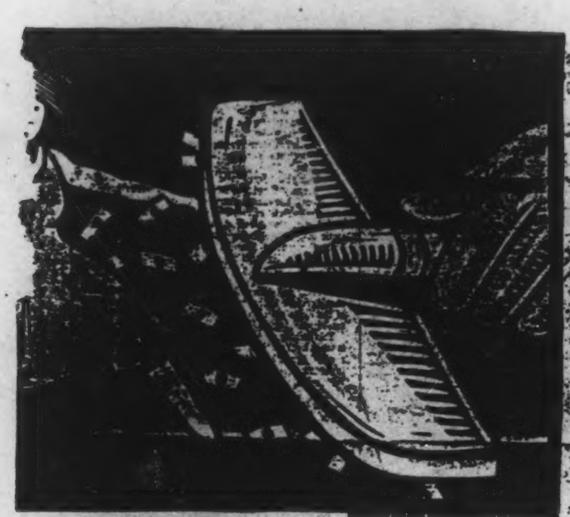

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appearance and reconstructive surgery to correct disfigurement caused by burns, surgery or birth defects.

- The American Association of Facial Plastic and Reconstructive Surgery, an affiliate of 2,800 plastic surgeons trained primarily as otolaryngologists (ear, nose and throat doctors). They usually, but not necessarily, restrict their practices to the head and neck. In a subtle put-down that escapes the notice of all but those directly involved, they have invented the term "general plastic surgeon" to refer to all those without ENT training. This implies that the "facial plastic surgeons" have a higher and more specific level of expertise.
- The American Society for Aesthetic Plastic Surgeons, a group composed of board-certified plastic surgeons who do mostly cosmetic rather than reconstructive procedures. An attempt was made in the 1970s to have this group declared a subspecialty of the general plastic surgeon organization, but nothing ever came of it.
- The American Association of Cosmetic Surgeons, whose 1,400 members by and large are certified in every specialty except plastic surgery: dermatology, general surgery, gynecology, ophthalmology, orthopedics, otolaryngology. This group holds workshops, sponsors four postdoctoral fellowships in cosmetic surgery, gives board certification examinations and is developing a two-year cosmetic surgery residency to begin in July at Graduate Hospital in Philadelphia.

An estimated 100,000 patients —almost all of them women—will undergo liposuction this year.

To some plastic surgeons, the activities of the cosmetic surgery association are cause for concern.

"There is no such thing as a aesthetic surgeon," says Fredericks. "It's a self-appointed appellation that an individual cloaks himself in. If an individual refers to himself as a cosmetic surgeon, the public should beware—he might not be properly trained."

"Patients who wish to look better in a bathing suit may not understand that there will be small scars and an lumpy skin surface."

—American Journal of [illegible]

Counters Newman, the cosmetic surgeon: "Just because they have the title plastic surgeon doesn't mean they know anything about cosmetic surgery. They can spend two years doing plastic surgery residencies, and they spend so much time doing cancer surgery, head and neck surgery, maxillofacial surgery, burn treatment, skin grafts, hand surgery that they do little or no cosmetic surgery. After two years, they're not experts in either."

For the past seven years, the American Association of Cosmetic Surgeons has been sponsoring weekend workshops, at $675 a session, to physicians—including plastic surgeons—interested in learning liposuction techniques. Although they are billed as "live," the sessions include no actual hands-on experience. Physicians sit in a hotel meeting room and observe bikini-clad models about to be suctioned. Then they huddle around the operating table, dressed in their surgical scrubs, to watch the procedure being done.

"It's a farce to pretend that's a course in surgery," says Mark Gorney, a San Francisco plastic surgeon. "Why would we want an individual to train for five years to be certified in general surgery, or seven years in plastic surgery, if we could take a weekend quickie course that would do the same [illegible]

The fact is, though, that licensed physicians don't even need the three-day course to be allowed to perform liposuction—or, for that matter, any other surgical procedure. All they need is an MD, a medical license, and a patient.

"If I wanted to, I could do brain surgery in my garage, and that would not be illegal," says Harvey Zarem, a plastic surgeon at the University of California at Los Angeles Medical Center. "It's stupid, but it's legal."

Liposuction may be more prone to this kind of career switch than almost any other procedure. Start-up costs are minor—a standard suction machine sells for about $4,000—and the potential income is enormous—$1,500 to $4,000 per operation, at the rate of at least several a day.

In addition, liposuction affords little chance for quality control. First, most are performed in doctors' offices rather than in hospitals. This eliminates one mechanism of quality control: hospital admitting privileges, given only to surgeons whose peers consider them to be qualified to perform particular procedures.

Second, because it is purely elective surgery, liposuction is not covered by medical insurance. This eliminates another form of quality monitoring: review by third-party payers who would resist having to foot the bill for operations they considered inappropriate.

A third form of quality control, board certification, is also jeopardized in liposuction. But this issue is more complicated than it first appears.

In the field of cosmetic surgery, there are two certifying boards: the National Board of Plastic and Reconstructive Surgery and the National Board of Cosmetic Surgery. But though their names sound similar, their requirements are not.

Only the plastic surgery board is recognized by the American Board of Medical Specialties, which works in cooperation with the American Medical Association. Plastic surgery is one of just 23 specialties that meet this group's requirements to be a distinct scientific field—rather than a new technique—with a sufficient number of accredited residency training programs nationwide.

The last new specialty added to the list, in 1979, was emergency medicine. The American Board of Medical Specialties is reviewing requests for new boards from two other specialities, medical management and legal medicine.

See LIPOSUCTION, Page 14

LIPOSUCTION, From Page 13

To be board-certified in plastic surgery, a medical school graduate must attend a residency in general surgery for three years, in plastic surgery for two to five years and must complete a two-day examination covering all aspects of plastic and reconstructive surgery.

The American Board of Cosmetic Surgery, in contrast, grants certification without the AMA's approval. To be board-certified in cosmetic surgery, a doctor must be board-certified in another surgical discipline, be in practice for five years, have performed 1,000 cosmetic procedures, including 200 in the previous year, and pass a two-day examination.

Plastic surgeons are upset when cosmetic surgeons use the designation "board certification," which they say confuses consumers.

And the 1,000 procedures requirement is meaningless, says plastic surgeon [illegible]. "I've hit a golf ball 1,000 times, but I don't qualify for the Masters," he says. "If you're not doing something right, what difference does it make how many times you do it?"

Cosmetic surgeons counter that liposuction is such a new procedure that most board-certified surgeons, no matter what their specialty, had no exposure to it during training. Board certification in dermatology, gynecology, otolaryngology or plastic surgery says nothing about whether a individual knows how to suction fat.

"Liposuction is a procedure, not a specialty," says Newman. "It transcends all areas of the body."

[illegible]

"Once physical exam, you can't tell the difference between a fat [illegible] and a tumor [illegible] under the skin," says Dr. [illegible], a plastic surgeon at the University of Pennsylvania School of Medicine. [illegible]

Nor should patients forget that liposuction is a risky procedure. [illegible]

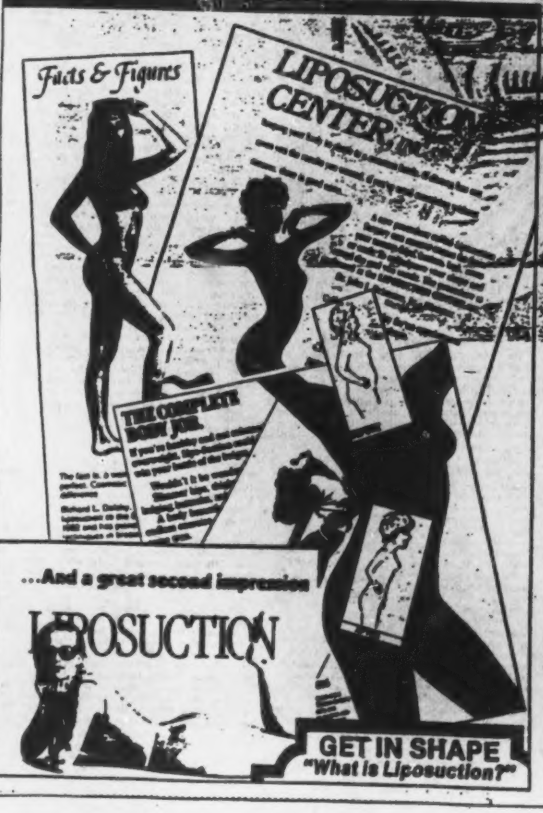
And there's another hazard: After all that, the result won't come that good. [illegible]

Most surgeons agree that liposuction helps a person look better in clothes but not necessarily better on the beach. [illegible]

Before accepting patients, surgeons are advised to establish what they expect of the surgery. [illegible]

But it's easy to see where they might have gotten the impression that liposuction would turn them into bathing beauties. Of the 23 advertisements from The Washington [illegible] collected for today's cosmetic surgery hearings on Capitol Hill, seven were exclusively advertising liposuction.

And every last one of them featured a model wearing a bathing suit.



About Body Wraps, Pills And Other Magic Wands For Losing Weight

by Judith Willis

Overweight and out of shape? Want to lose pounds without dieting and eliminate inches without exerting any effort?

So do millions of Americans who believe that somehow, as if by waving a magic wand, they will be thin and firm. Unwilling or unable to lose weight through diet and exercise, they turn to weight-loss gimmicks ranging from pills that supposedly let them eat unlimited pasta to rubber suits that make them sweat while they sleep.

Most current diet gimmicks seem to fall into two categories: (1) custom garments or body wraps that claim to "melt" fat away in a short time, and (2) pills that supposedly curb appetites without side effects, or allow dieters to eat as much as—or more than—normal and still lose weight. The pills are usually touted as the product of some previously undiscovered process.

Who can blame the fretfully flabby for being lured by the promise of losing inches without doing anything more strenuous than popping a pill or wrapping up the offending flesh? Who can resist ads for body wraps that promise "to burn away fat even while you sleep," to "lose 4-6 inches the first day"?

Some of the plastic or rubber garments are worn around the waist, some cover the waist, hips and thighs, and others cover nearly the entire body.

Some are to be worn while carrying out routine activities, others while exercising, and some while sleeping. One is inflated with air from a vacuum cleaner. Another uses an electric hair dryer to blow in warm air. Some are used after a cream, gel or lotion is applied or after the wrap is soaked in a solution.

The Food and Drug Administration has investigated a number of these products and has taken action against several promoters of wrapping devices and latex exercise or sweat suits for making unsubstantiated medical or therapeutic claims.

The garments and wraps, with or without lotions and creams, reduce body dimensions by removing fluids. Most medical experts agree that such treatment will cause a loss of inches and perhaps pounds due to profuse perspiration, but the reductions are temporary. The fluid is soon replaced by drinking or eating. But rapid and excessive fluid loss is potentially dangerous because it can bring on severe dehydration and can upset the balance of important electrolytes in the body.

Wraps have no effect on fat deposits and will not dissolve fat, even temporarily. Fat is not broken down by perspiration. It is gotten rid of only when fewer calories are consumed than are needed to meet the body's energy requirements.

The latest twist in the body wrap bonanza is a product called La Creme, a cream to be applied to parts of the body where loss of inches is desired. La Creme differs from other wrap products in that the wrap is not sold along with it. Rather, consumers may choose their own wraps from among the plastic products normally used to wrap food. La Creme is applied and then six or seven layers of the plastic wrap are wound around the creamed area.

A leaflet for the product claims: "Lose up to two inches from those problem areas in just one hour." An advertisement adds, "Its gentle warmth penetrates into your skin and helps melt fatty deposits." But, as with other wraps, any weight or inches that disappear are lost from perspiration. (See "Fat Won't Melt," an Update in the November 1981 *FDA Consumer*.)

Promotional literature distributed to retail outlets, such as department stores and specialty salons, claimed that FDA had approved or classified La Creme as a skin toner, tightener and smoother. In truth, FDA had never been given an opportunity to evaluate the product and had no idea what it contained.

FDA advised a distributor of La Creme that, based on the product's labeling, it should be regulated as a drug because it claimed to alter the size, shape or conformity of the body—a drug function as defined by the federal Food, Drug, and Cosmetic Act. When the distributor contended that La Creme was a cosmetic and therefore not subject to safety and efficacy requirements, FDA replied that claims of even temporary reduction of body measurements were not appropriate to a cosmetic.

The company has not replied to FDA's comments. In the meantime, many of the department stores that carried La Creme have stopped selling it.

In resorting to magical slimming items, the weight conscious are often either taking risks with untested products that may alter the body's functioning or being duped by products that have no more effect than a placebo.(Only two drugs—phenylpropanolamine and benzocaine, along with caffeine—should be used in non-prescription diet aids, according to an FDA advisory panel. Those recommendations have not been acted on by the agency.)

Yet, the marketing of untested diet aids persists. They appear on the market without FDA approval because manufacturers often contend that their product is a food and thus not subject to premarket approval from FDA as a drug would be.

Often a product does not come to FDA's attention until it has been used by a substantial number of persons, some of whom may be harmed by it.

Starch blockers are an example of a product sold as a food but considered by FDA to be a drug. Advertised and sold nationwide, starch blockers allegedly block or impede starch digestion and thus help in weight control and weight reduction. One manufacturer touted the product as "a revolutionary new concept in natural weight control." Print and TV ads claimed people taking starch blocker pills could eat up to 600 calories a day of foods such as bread, potatoes and pasta without absorbing the calories.

Manufacturers did not seek FDA approval before putting starch blockers on the market. They claimed the product, prepared from raw beans, was a "special dietary food" instead of a drug.

FDA disagreed. The agency asked the manufacturers to discontinue marketing starch blockers until scientific testing could confirm their safety and efficacy as drugs.

Users of these products have complained to FDA of nausea, vomiting, diarrhea and stomach pains. The pills are considered to be particularly hazardous to diabetics, who may rely on their purported carbohydrate-blocking effect to calculate their diets.

Although these products are made from a food substance, FDA considers them to be drugs because of the claim that they control or reduce weight by blocking or interfering with digestion. According to the starch blocker theory, the pills contain a substance that inhibits the activity of the enzyme amylase, which digests carbohydrates. This constitutes a drug action that may interfere with the body's normal metabolism. Under the FDC Act, a substance that is offered for a non-food purpose and that affects a function of the body is a drug, not a food, even if it is derived from a vegetable.

Another natural substance promoted as a weight-loss wonder is spirulina. It is sold as a food or food supplement in the form of a dark green powder or pill in many health food stores. Spirulina is one of about 1,500 known species of blue-green algae that grow in brackish ponds and lakes in mild and hot climates throughout the world. Pure spirulina is a source of protein and contains a number of vitamins and minerals. However, in the amounts normally consumed when taken according to label directions, the nutrients derived are insignificant. As a food, spirulina can be legally marketed as long as it is labeled accurately and contains no contaminated or adulterated substances.

Claims have been made that phenylalanine, an amino acid found in spirulina (and in most other protein sources), "acts on the brain's appetite center to switch off your hunger pangs." However, an FDA advisory panel reviewing data on phenylalanine in 1979 found no reliable scientific data to demonstrate that it is safe and effective as an appetite suppressant.

Some nutritionists fear that consuming large amounts of spirulina might have an effect similar to that of the liquid protein diets which resulted in heart problems and even death for some dieters. Helene Swenerton, a nutritionist at the University of California's Davis Cooperative Extension, points out that because algae are single-celled organisms, they are rich in nucleic acids providing not only a lot of protein but also large amounts of uric acid, which could result in kidney stones or gout.

Another, more recently introduced "natural" pill is dubbed "Glucomannan." Advertised as the "Weight Loss Secret That's Been In The Orient For Over 500 Years," Glucomannan apparently is chemically processed from the konjac root, which has been used as a food in Japan and other Oriental countries for many years.

A search of both the Japanese and English language medical literature, however, shows no studies of this food as a weight-loss product. The manufacturer has not supplied FDA any information to substantiate its claims. According to advertising, Glucomannan "helps transport food through your digestive system faster. . . . As a result, more of the calories you do take in (and you're likely to take in fewer, to begin with) can pass out of your system, still undigested, to help your weight loss along even further."

The manufacturer originally claimed that its pill was a food. When FDA wouldn't accept that claim, the firm maintained that its product was GRAS (generally recognized as safe) because it was commonly used in food prior to 1958.

FDA responded that although konjac tubers have been used as food in the United States since at least 1899, the substance in Glucomannan is a chemically processed extract from konjac tubers. This substance is not GRAS for food use and does not have a history of food use in this country before 1958. (Under the food additive law passed by Congress in 1958, any substance intended for food use has to be either GRAS or permitted under a food additive regulation. Substances commonly used as food prior to 1958 are generally recognized as safe.) FDA said that to be marketed as a food substance, Glucomannan would have to either be affirmed as GRAS or approved as a food additive. Both of these require submission of scientific data to FDA.

In addition to miracle pills with unproven claims, another type of dieter's delusion is still being perpetrated by some diet clinics years after both the FDA and the American Medical Association stated it was useless for weight loss.

This deceptive practice is injection with HCG (human chorionic gonadotropin). HCG is a hormone extracted from urine of pregnant women. It is approved by FDA for treatment of certain problems of the male reproductive system and in stimulating ovulation in women who have had difficulty becoming pregnant. No evidence has been presented, however, to substantiate claims for HCG as a weight-loss aid.

An article in *JAMA* (*Journal of the American Medical Association*) in 1974 stated:

"No convincing scientific evidence exists that human chorionic gonadotropin has any pharmacologic effect in weight reduction. Hence, claims to the public that such effects do occur are a misrepresentation of the scientific facts."

FDA requires all labeling and advertising of HCG to state that it has not been demonstrated to be effective in the treatment of obesity. The ads must also state that HCG is not approved by FDA as safe and effective in treatment of obesity or weight control.

Yet the use of HCG for weight loss continues. For instance, advertisements for weight-loss clinics using HCG appeared in the Chicago area in the summer of 1982. The ads included the required disclaimer, but in type much smaller than that used to extol the virtues of the clinics' program.

The pill or shot to enable a person to lose weight without danger and without eating less has not been formulated. And the garment or other device to let one firm up or lose inches without moving a muscle has yet to be invented.

It looks like those who want to be slim will have to resort to those old, unglamorous standbys—eating less and exercising more—to shake those excess pounds.

At least until the next waving of the magic wand.

Judith Willis is editor of FDA's Drug Bulletin, *a periodical for health professionals.*

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FDA CONSUMER

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Public Health Service
Food and Drug Administration
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Rockville, Md. 20857

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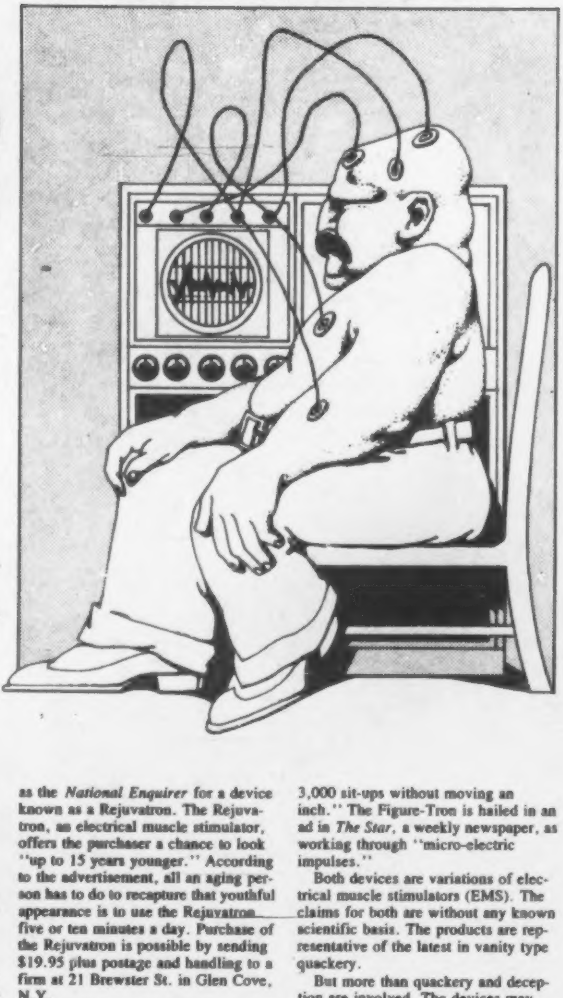
EMS
Fraudulent Flab Remover



by Roger W. Miller

Not only was Ponce de Leon right but so was Robert Hutchins, or so some advertisers of electrical muscle stimulators would have us believe.

As anyone who ever attended the fourth grade in a U.S. school knows, Ponce de Leon was the Spanish explorer who was sure that there was a fountain of youth down among the alligators in Florida.

Robert Hutchins, as academia trivia fans may know, was the former head of the University of Chicago who once said:

"When I feel the urge to exercise, I lie down."

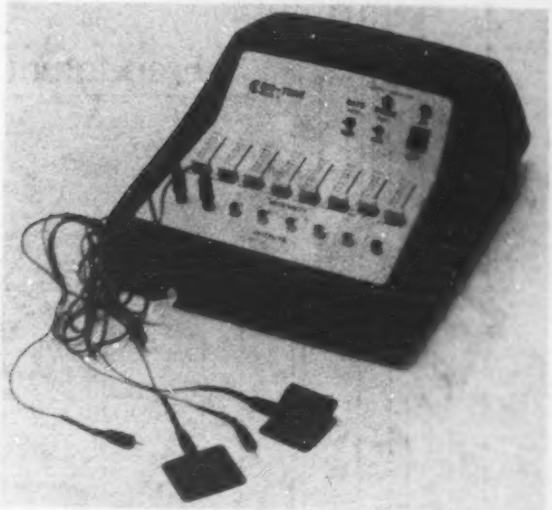
Ponce de Leon's vindication comes in the form of ads in such publications as the *National Enquirer* for a device known as a Rejuvatron. The Rejuvatron, an electrical muscle stimulator, offers the purchaser a chance to look "up to 15 years younger." According to the advertisement, all an aging person has to do to recapture that youthful appearance is to use the Rejuvatron five or ten minutes a day. Purchase of the Rejuvatron is possible by sending $19.95 plus postage and handling to a firm at 21 Brewster St. in Glen Cove, N.Y.

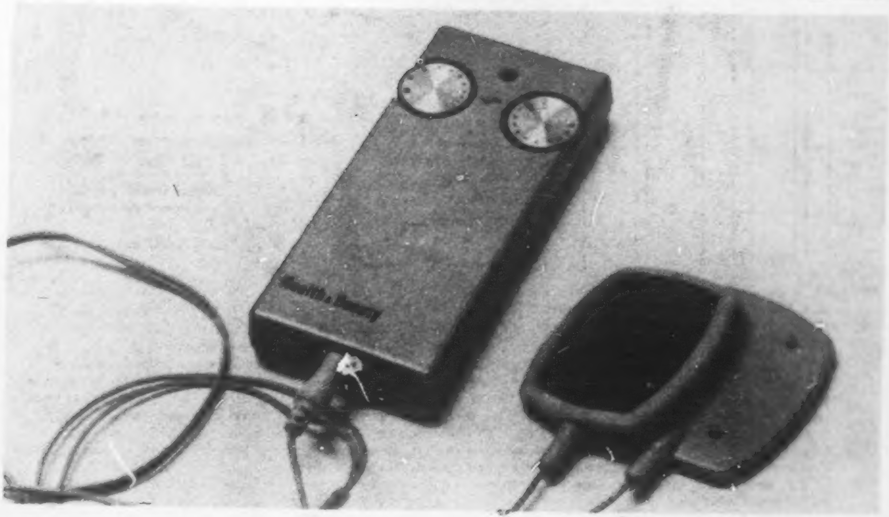
Robert Hutchins' wisdom is borne out by sending a like amount to the same address for a Figure-Tron that provides "all the figure-toning of 3,000 sit-ups without moving an inch." The Figure-Tron is hailed in an ad in *The Star*, a weekly newspaper, as working through "micro-electric impulses."

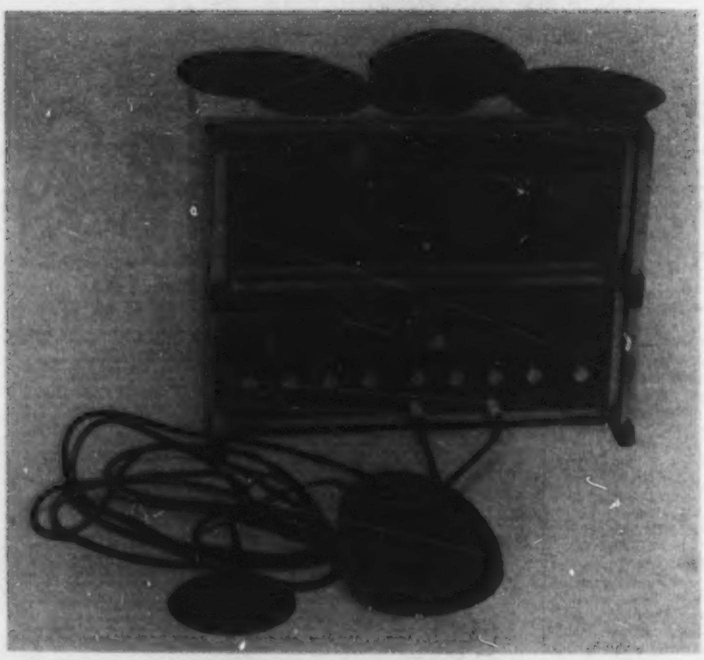
Both devices are variations of electrical muscle stimulators (EMS). The claims for both are without any known scientific basis. The products are representative of the latest in vanity type quackery.

But more than quackery and deception are involved. The devices may also be dangerous if misused.

Like many quack gimmicks, the EMS devices have a legitimate legacy. Electrical muscle stimulators are used







Electrical muscle stimulators (EMS) come in various sizes and shapes. At left is a Health and Beauty model made in Hong Kong. Above that (upper left) is a model called a Biotone IV, made in the United States. At the top of this page is an Italian Model called a Vibro Electronic II. Such EMS units are often promoted as "body shapers" and "passive exercise" devices, but they should only be used by a trained health practitioner for specific medical purposes.

for physical therapy in the treatment of medical diseases and related medical conditions. They may be promoted, labeled, used, offered for use, etc..*only* for such purposes. When so used, they are considered safe and effective.

However, they are not to be sold through the mail or without a prescription and should be used only under the supervision of a licensed practitioner.

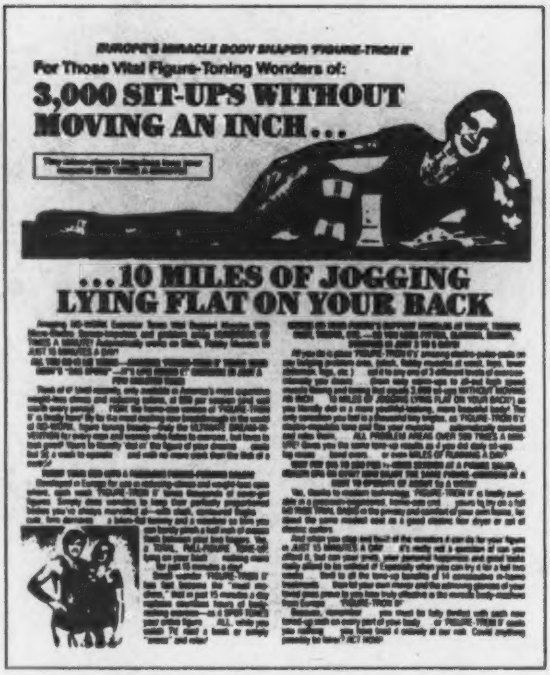
Among the legitimate medical uses:

- To relax muscle spasms
- To prevent blood clots in leg muscles of bedridden patients after a stroke or surgery
- To increase blood circulation to a part of the body
- To increase or monitor the range of motion of an arm or leg
- To retard or prevent muscle atrophy due to disuse

Those purposes are a far cry from home use for a face lift without surgery or health spa use for "slimming and trimming," weight loss, "body shaping and contouring," bust development, wrinkle removal, spot reducing and removal of so-called cellulite.

The Food and Drug Administration, which regulates the use of EMS devices, has not seen any evidence that electrical muscle stimulators are safe and effective for home use or for the touted uses in health spas and beauty salons. FDA considers muscle stimulators promoted or used for these purposes to be misbranded and fraudulent, even if a physician or other licensed practitioner is using the device.

Cosmetologists are licensed in some states to use EMS devices, but FDA's



EUROPE'S MIRACLE BODY SHAPER "FIGURE-TRON II"

For Those Vital Figure-Toning Wonders of:

3,000 SIT-UPS WITHOUT MOVING AN INCH...

...10 MILES OF JOGGING LYING FLAT ON YOUR BACK

The ad at right is typical of the promotions for EMS units. It is also typical of health fraud advertisements with its promises that sound too good to be true; the overuse of boldface type, capitalization and exclamation marks; the pseudo-scientific language; and such standard come-on words as "miracle," "amazing," "sexier" and "exciting."

position is that cosmetologists don't have the training to diagnose and treat medical conditions for which the stimulators might be properly used.

Potential hazards from EMS devices include electrical shocks and burns. In addition, the devices should not be used on pregnant women, persons with heart problems, particularly those who wear pacemakers, and people who have cancer or epilepsy. Finally, the EMS electrodes should not be placed where a strong current could pass through the heart, brain or spinal column.

Despite the potential for harm, EMS units have appealed to what might be called armchair joggers. And promotions have been aimed at this type of person. The health spas have claimed that a trim body can be realized with "the most sophisticated machines that do all the work." One ad in the *Los Angeles Times* spoke of "passive exercise" that could be done while "you rest, read or watch TV."

According to various newspaper accounts, the cost of all this easy exercise is $25 to $30 an hour. A dozen or so sessions are usually recommended. The mail-order firms make a big point of the per-session costs at beauty and health spas, and they stress that a person can buy an EMS device for less than the cost of one session. It seems there is quite a bit of competition among quacks.

Through February 1983 FDA has carried out seizures against 19 firms that were selling or using the stimulators improperly. In addition, 14 import detentions were made in the fiscal year ending Sept. 30, 1982.

Among the seizures were 62 Figure-Tron devices, seized by court order at Consumer Fulfillment Inc. of Glen Head, N.Y. Although advertised as "Europe Miracle Body Shaper," it turns out that the devices were manufactured in Hong Kong. So even the deception is deceptive.

The current generation of electrical muscle stimulators is similar to the Relaxacisor, an EMS device sold without prescription until 1970. Distribution of the device was banned after FDA won a five-month court trial in which 40 witnesses testified that they suffered varying degrees of injury while using the machine.

So history is not being rewritten. Even if Ponce de Leon were alive today, he would search in vain for a fountain of youth. And Robert Hutchins' remedy for the urge to exercise hasn't been proven out by electrical muscle stimulators.

Roger W. Miller is editor of FDA Consumer.

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FDA CONSUMER

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May 10, 1989

The Honorable Ron Wyden
U.S. House of Representatives
1406 Longworth House Office Bldg.
Washington, D.C. 20515

Dear Congressman Wyden:

I have just read the account of your subcommittee hearings on cosmetic surgery and your call for restrictions on physician advertising. This whole episode would be laughable if it were not so tragic.

The American Medical Association had ethical guidelines for advertising until the Federal Trade Commission got into the act. In the late 1970s the FTC decided that the professions were restraining trade and competition by putting restrictions on members' advertising. The arguments made by the AMA were doggone near identical to the statements you made at the subcommittee hearing.

At a hearing in California more than ten years ago the AMA found a half-dozen women who had been disfigured after going to "cosmetic surgeons" who were not qualified to do what they advertised they could do. These women testified that they never would have gone to these doctors if they had not seen the ads in the paper. The AMA argued that this was good reason to allow medical societies to enforce the ethical guidelines on advertising, but the Administrative Law Judge ruled the testimony was irrelevant and that the AMA restrictions were anti-competitive.

Since that time, physician advertising has run amok. How ironic that you now ask the FTC to get tough when it was the FTC that opened the Pandora's box in the first place.

The FTC is responsible for the situation you described to the subcommittee, and physicians who in good faith try to control the renegades face the same antitrust and restraint of trade action as the bad faith attempts which destroyed the medical community in Astoria, Oregon.

How sad.

Very truly yours,

Jim Koch

James A. Koch
Executive Vice President

JAK:jmj

April 26, 1989

Congressman Ron Wyden
2452 Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Representative:

Your hearings are of special interest to me. I had two cosmetic procedures performed by a Plastic Surgeon in my area in 1985. The frustration and confusion I experienced in trying to determine who was qualified to perform the procedures was exacerbated by the plethora of advertisements I encountered. Other women have related similar experiences to me.

Magazine articles I read cautioned me to be sure that the surgeon I selected was "board certified". This only added to my confusion. When I inquired about a surgeon's qualifications, everyone said they were "board certified". The Cosmetic Surgeons claimed to be "board certified" and fully qualified to perform cosmetic procedures by the American Academy of Cosmetic Surgeons. Plastic Surgeons claimed to be board certified by the American Society of Plastic and Reconstructive Surgeons.

My question is: If Plastic and Reconstructive Surgeons are the "real board certified" surgeons, why are the other (cosmetic) surgeons allowed to advertise and claim "board certification"?

The situation in our area is more confusing today than it was in 1985 when I was trying to determine who was qualified to perform my sugery. Today, there are gynecologists, dermatologists and general surgeons advertising and performing cosmetic sugery. Recently, a woman died during sugery being performed by one of the local cosmetic surgeons.

I hope your hearings lead to meaningful regulatory legislation.

Sincerely,

Sandra J. Wessel
1061 Pebble Beach Dr.
Upland, Ca. 91786

**FACIAL
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Howard A. Tobin, M.D., F.A.C.S.
Certified American Board of Cosmetic Surgery

May 19, 1989

Mr. Frank Papineau
Rm: B-363
House Rayburn Office Bldg.
Washington, D.C. 20515

Dear Frank:

I have been following the progress of the congressional hearings with interest. What has been most striking to me was the fact that when the American Medical Association News covered the subject, a balanced report followed. It fairly pointed out the strengths and weaknesses of both sides of the issue. Unfortunately, in the lay press, the coverage was far from balanced. Once again, we found that our adversaries, with their more established connections and better funding, managed to convince the lay press that they were the heros and we were the villains.

As I see the thrust of your subcommittee's efforts, it is apparent that advertising and accreditation are the two main issues that concern you.

In regard to advertising, we all realize that advertising should basically be truthful and honest and should not be misleading to the public. However, a balanced approach is essential. In truth, far more advertising is carried out by plastic surgeons than by cosmetic surgeons. Not only do we see individual plastic surgeons advertising their practice, but we are faced with a concerted advertising campaign by organized plastic surgery to discredit the rest of us who have a legitimate right to practice our specialty. As an example, I have enclosed some information that is part of a campaign by the Dallas Society of Plastic Surgeons, which through innuendo and statements taken out of context, attempts to present a strong statement that cosmetic surgeons are all ill trained hucksters. All of this done in the name of protecting the public!

If, indeed, your subcommittee is truly interested in the public, then I think you owe it to those of us who are truly intersted in providing the public with the highest level of cosmetic surgical services to strongly discourage this type of smear campaign.

You know from your experience in working with us that we are willing to cooperate with all positive suggestions that are truly in the public's interest. It is unfair for you to ask us to only give without offering some help to us in areas where we are being unfairly oppressed.

Sincerely,

Howard

Howard A. Tobin, M.D., F.A.C.S.

HAT/wl

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